Exhibit B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2875
	)	HONORABLE ROBERT B. KUGLER, DISTRICT COURT JUDGE

RULE 30 VIDEOTAPED DEPOSITION
PHILIP JAMES RUSS
THURSDAY, JANUARY 5, 2023

JOB NO. 5648472
REPORTED BY: DAYNA HESTER, C.S.R. 9970

VIDEOTAPED DEPOSITION OF PHILIP JAMES RUSS, TAKEN ON BEHALF OF DEFENDANTS, AT 9:20 A.M., THURSDAY, JANUARY 5, 2023, AT GREENBERG TRAURIG LLP, 1840 CENTURY PARK EAST, SUITE 1900, LOS ANGELES, CALIFORNIA, WITH MULTIPLE PARTICIPANTS APPEARING REMOTELY, BEFORE DAYNA HESTER, C.S.R. NO. 9970, PURSUANT TO NOTICE.

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I N D E X

QUESTIONS INSTRUCTED BY COUNSEL NOT TO ANSWER

(NONE.)

E X H I B I T S

-- EXHIBITS CONTINUED ON NEXT PAGE --

E X H I B I T S (CONTINUED)

-- EXHIBITS CONTINUED ON NEXT PAGE --

E X H I B I T S (CONTINUED)

EXHIBIT NO.	PAGE	DESCRIPTION
EXHIBIT 13	159	FILE TITED "EXHIBIT 0013 - 32 - TEVA-MDL2875-00020279.PDF"
EXHIBIT 14	161	FILE TITLED "EXHIBIT 0014 - 34 - TEVA-MDL2875-00020213.PDF"
EXHIBIT 15	162	FILE TITLED "EXHIBIT 0015 - 31 - QUALITY POLICY SOP CORP 0001.PDF"
EXHIBIT 16	169	FILE TITLED "EXHIBIT 0016 - 10 - VALSARTAN, USP (SUBSTANCE) USP 44 LAST ACCESSED 221115.PDF"
EXHIBIT 17	173	FILE TITLED "EXHIBIT 0017 - 11 - VALSARTAN TABLETS USP MONOGRAPH USP 44 LAST ACCESSED 221115.PDF"
EXHIBIT 18	180	FILE TITLED "EXHIBIT 0018 - 12 - VALSARTAN AND HYDROCHLOROTHIAZIDE TABLETS USP MONOGRAPH USP 44 LAST ACCESSED 221117.PDF"
EXHIBIT 19	182	FILE TITLED "EXHIBIT 0019 - 15 - Q3A(R)-IMPURITIES-IN-NEW-DRUG-SUBSTANCES.PDF"
EXHIBIT 20	183	FILE TITLED "EXHIBIT 0020 - 16 - 2006 - ICH Q3B (R2) IMPURITIES IN NEW DRUG PRODUCTS.PDF"
EXHIBIT 21	185	FILE TITLED "EXHIBIT 0021 - TAB %5B %5D - AUGUST 30, 2018 - STATEMENT OF S. GOTTLIEB MD (FDA) RE VALSARTAN (HIGHLIGHTED).PDF"
EXHIBIT 22	194	FILE TITLED "EXHIBIT 0022 - TAB %5B %5D - JANUARY 25, 2019 - STATEMENT OF S. GOTTLIEB MD (FDA) RE VALSARTAN (HIGHLIGHTED).PDF"
EXHIBIT 23	210	FILE TITLED "EXHIBIT 0023 - 38 - TEVA-MDL2875-00950662.PDF"

-- EXHIBITS CONTINUED ON NEXT PAGE --

E X H I B I T S (CONTINUED)

EXHIBIT NO.	PAGE	DESCRIPTION
EXHIBIT 24	211	FILE TITLED "EXHIBIT 0024 -TEVA-MDL2875-00020264_CONFIDENTIAL .PDF"
EXHIBIT 25	346	DOCUMET TITLED "EXHIBIT 25 - SIGNED PROTECTIVE ORDER"
EXHIBIT 26	220	FILE TITLED "EXHIBIT 0026 - 39 - TEVA-MDL2875-00950663.PDF"
EXHIBIT 27	220	FILE TITLED "EXHIBIT 0027 - TEVA-MDL2875-00020268_HIGHLY CONFIDENTIAL.PDF"
EXHIBIT 28	228	FILE TITLED "EXHIBIT 0028 - TEVA-MDL2875-00020257_CONFIDENTIAL. PDF"
EXHIBIT 29	N/A	(NO EXHIBIT DESIGNATED)
EXHIBIT 30	247	FILE TITLED "EXHIBIT 0030 - B-2021.06.05-6 SUSHIL JAISWAL, PH.D. (MINI).PDF"
EXHIBIT 31	293	FILE TITLED "EXHIBIT 0031 - B-TORRENT-MDL2875-00010961.PDF"
EXHIBIT 32	297	FILE TITLED "EXHIBIT 0032 - B-TORRENT-MDL2875-00004362.PDF"
EXHIBIT 33	316	DOCUMENT TITLED "EXHIBT 33 - ICH GUIDELINE Q9 ON QUALITY RISK MANAGEMENT"
EXHIBIT 34	318	DOCUMENT TITLED "EXHIBIT 34 - SECITON 351. ADULTERATED DRUGS AND DEVICES"
EXHIBIT 35	323	DOCUMENT TITLED "EXHIBIT 35 - ZHEJIANG HUAHAI PHARMACEUTICAL - 566685 - 11_29_2018 _ FDA"

LOS ANGELES, CALIFORNIA

THURSDAY, JANUARY 5, 2023; 9:20 A.M.

THE VIDEOGRAPHER: Good morning. 09:20
We're going on the record at 9:20 a.m. on 09:20
January 5th, 2023. 09:21
Please note that microphones are sensitive 09:21
and may pick up whispering and private conversations. 09:21
Please mute your phone at this time. 09:21
Audio and video recording will continue to 09:21
take place unless all parties agree to go off the 09:21
record. 09:21
This is Media Unit 1 of the video-recorded 09:21
deposition of Philip Russ taken by counsel for the 09:21
defendants in the matter of Valsartan Products 09:21
Liability Litigation filed in the U.S. District Court 09:21
for the District Court of New Jersey. 09:21
The location of this deposition is 09:21
1840 Century Park East, 19th Floor, Los Angeles, 09:21
California. 09:21
My name is Julian Abalos representing 09:21
Veritext Legal Solutions. I am the videographer. 09:21
The court reporter is Dayna Hester from the 09:21
firm Veritext Legal Solutions. 09:21
I am not related to any party in this 09:21

action, nor am I financially interested in the 09:21
outcome. If there are any objections to the 09:21
proceeding, please state them at the time of your 09:21
appearance. 09:21
Counsel in person will now state their 09:21
appearances and affiliations for the record beginning 09:21
with the noticing attorney. 09:21
MS. LOCKARD: Good morning. 09:21
This is Victoria Lockard from Greenberg 09:22
Traurig. I represent the Teva defendants. 09:22
Here with me today is Steve Harkins also 09:22
representing the Teva defendants from Greenberg 09:22
Traurig. 09:22
MR. STANOCH: David Stanoch of Kanner & 09:22
Whiteley for plaintiffs and the witness. 09:22
MS. LOCKARD: Just for the record, we have a 09:22
number of individuals who are representing various 09:22
parties on the phone. 09:22
We are going to dispense with their 09:22
introductions, and we will have them submit their 09:22
appearances in writing to the court reporter at a 09:22
break. 09:22
MR. HARKINS: One -- one moment before -- I 09:22
did receive a request from one of the remote counsel 09:22
to get a realtime link. 09:22

Page 14

Can they request that from someone there, or 09:22
do you need to send it to them? 09:22
THE REPORTER: Can we go off the record? 09:22
MS. LOCKARD: Go off the record. 09:22
THE VIDEOGRAPHER: Off record at 9:23 a.m. 09:22
(Brief recess.) 09:22
THE VIDEOGRAPHER: And we are back on record 09:26
at 9:26 a.m. 09:26
THE REPORTER: Okay. Hold on one second. 10:08
This is a federal case; so I have a read-on. 10:08
My name is Dayna Hester. This statement is 10:08
to acknowledge my obligations pursuant to Federal 10:08
Rules of Civil Procedure. 10:08
Rule 30(b), Subsection 5(a). My business 10:08
address is 707 Wilshire Boulevard, Los Angeles, 10:08
California. The videographer has stated the 10:08
additional required information.
Rule 30(b), Subsection 5(c). Upon
completion of the deposition, if there is a
stipulation about the custody of the transcript or
other pertinent matters, I will recite such
stipulation(s). Additionally, the videographer will
read-off when the deposition concludes.
So with this being said, I will now swear in
the witness.

Page 15

Mr. Russ, please raise your right hand.
THE WITNESS: [Witness did as requested].
THE REPORTER: Do you affirm the testimony
you are about to give in the cause now pending will be
the truth, the whole truth, and nothing but the truth? 09:27
THE WITNESS: Yes. 09:27
THE REPORTER: Thank you. 09:27

PHILIP JAMES RUSS
having been first duly sworn, was
examined and testified as follows:

EXAMINATION
BY MS. LOCKARD:
Q. What is your full name? 09:27
A. Philip James Russ. 09:27
Q. Where do you live? 09:27
A. I live in Palm Springs, California. 09:27
Q. What is your address? 09:27
A. 2157 Casitas Way, Palm Springs. 09:27
Q. Where do you practice or where is your 09:27
professional location? 09:27
A. My professional location is also at 09:27
2157 Casitas Way in Palm Springs. 09:27
Q. You don't maintain a separate office? 09:27

Page 16

A. I do not. 09:27
Q. What do you do for a living? 09:27
A. I do management consulting for regulatory 09:27
compliance for products that are regulated by the 09:27
food and drug administration as well as other 09:27
regulatory bodies across the world: 09:27
pharmaceuticals, medical devices, biologics. 09:27
Q. Any work in the food industry? 09:28
A. No. 09:28
Q. What about supplements? 09:28
A. I'm familiar with supplement regulations, 09:28
but up to this point, I have not had any clients for 09:28
supplements. 09:28
Q. So you don't consider yourself an expert 09:28
in the supplement area at this point? 09:28
MR. STANOCH: Objection to form. 09:28
Go ahead. 09:28
THE WITNESS: I wouldn't say I'm not an 09:28
expert in that I understand the regulations. But all 09:28
I'm saying is I haven't practiced in that area because 09:28
I haven't had a client who has a need in that area. 09:28
BY MS. LOCKARD: 09:28
Q. What is your understanding of your role in 09:28
this case? 09:28
A. I was asked to opine on the 09:28

Page 17

Defendants Teva and Torrent's GMP practices as it 09:28
relates to the incident of genotoxic impurities in a 09:28
Valsartan product from ZHP, a Chinese manufacturer 09:29
of that drug substance. 09:29
Q. And are you offering opinions today about 09:29
any other defendant in this case, other than Torrent 09:29
and Teva? 09:29
A. No. 09:29
Q. Are you under any medications or suffering 09:29
from any medical conditions today that would prevent 09:29
you from hearing and understanding my questions? 09:29
A. No. 09:29
Q. In this case, we have a protective order 09:29
governing the use and disclosure of confidential 09:29
information. 09:29
Are you familiar with such protective 09:29
orders? 09:29
A. Yes. 09:29
Q. Have you seen one in this case? 09:29
A. I'm not completely sure. I -- it may have 09:29
been provided to me in discovery. I would have 09:29
to -- along with the production of documentation I 09:29
should have. I'm not sure. 09:29
Q. Okay. I'll have the confidential and 09:29
protective order marked as Exhibit 1, and I'll just 09:29

Page 18

give you a copy of this. 09:29
(Deposition Exhibit 1 was marked for 09:29
identification and is attached hereto.) 09:29
THE WITNESS: Okay. 09:29
BY MS. LOCKARD: 09:29
Q. We don't have evidence that you have 09:29
signed this as an expert. There is an affidavit or 09:30
an exhibit at the back that -- where the order -- 09:30
the experts who are provided confidential documents 09:30
and information are required to sign indicating they 09:30
agree to keep the confidential documents and highly 09:30
confidential documents as such. 09:30
Do you understand that? 09:30
A. I do most certainly, yes. 09:30
Q. Okay. And in your business, you are 09:30
familiar with such confidential obligations and 09:30
requirements for these cases and in your regular 09:30
practices; is that right? 09:30
A. Absolutely. 09:30
Q. So do you agree to keep any confidential 09:30
documents or highly confidential documents that you 09:30
have been provided confidential in this case and do 09:30
not disclose them beyond the use in the litigation? 09:30
A. Yes. 09:30
Q. Okay. You are welcome to take a look at 09:30

Page 19

this agreement over a break if you need to. 09:30
MS. LOCKARD: But we would ask that he sign 09:30
the exhibit today at some point. 09:30
MR. STANOCH: We'll provide the signed 09:30
version he has, or we'll sign it again at the break, 09:30
Counsel. Not a problem. 09:30
MS. LOCKARD: Sure. 09:30
BY MS. LOCKARD: 09:30
Q. Okay. Mr. Russ, did you bring anything 09:30
with you today? 09:31
A. No. 09:31
Q. All right. Let's -- I'm going to give you 09:31
a copy of your -- the notice of videotaped 09:31
deposition of Philip Russ. This will be Exhibit 2. 09:31
Have you seen a copy of this? 09:31
MR. STANOCH: Counsel, I'm just asking how 09:31
would you like to mark the exhibits for the record. I 09:31
don't care. Just how you would do it. 09:31
MS. LOCKARD: I want to get a sicker on 09:31
them, and we can do that. I just roll through so 09:31
we'll -- when you get chance, you can -- 09:31
MR. STANOCH: All right. 09:31
MS. LOCKARD: We're also -- are we providing 09:31
them in the Dropbox? 09:31
MR. HARKINS: I can, yes. 09:31

Page 20

MS. LOCKARD: Okay. That may be easier just 09:31
to double-check. 09:31
1 for the protective order; and 09:31
2 for the notice of video deposition. 09:31
(Deposition Exhibit 2 was marked for 09:31
identification and is attached hereto.) 09:31
BY MS. LOCKARD: 09:31
Q. All right. So, Mr. Russ, have you seen a 09:31
copy of Exhibit 2? 09:31
A. I have not. 09:31
Q. All right. If you will take a look at it 09:31
here with me. It's the document that relates to 09:32
your deposition today in this case. 09:32
And on Page 6 of the document, there is a 09:32
set of requests that we propounded through 09:32
plaintiffs' counsel requesting that you bring 09:32
certain items with you to your deposition today. 09:32
Do you see those? 09:32
A. [Witness reviews document]. 09:32
I do. Yes. 09:32
Q. Okay. My understanding as to what you 09:32
provided so far in this case to counsel and that's 09:32
been disclosed to us so far includes -- obviously 09:32
your report, your CV, your statement of materials 09:32
considered, your invoices, and your retention 09:32

Page 21

letter. 09:32
A. Yes. That makes sense to me. 09:32
Q. Have you received any other materials 09:33
other than those that would be contained in a hard 09:33
copy file, paper file? 09:33
A. You mean have I received documents in 09:33
electronic format? 09:33
Q. In a non-electronic format. In paper. 09:33
A. No. I have not received anything in 09:33
non-electronic format. 09:33
Q. Do you keep any hard files, paper files 09:33
involving this case and your involvement in it? 09:33
A. No, I don't. 09:33
Q. So everything you have received or 09:33
reviewed would be in an electronic file somewhere on 09:33
a computer of yours? 09:33
A. Yes. 09:33
Q. Okay. Have you retained everything that 09:33
you have been provided in this case by counsel? 09:33
A. I have. Yes. 09:33
Q. You have not destroyed or discarded or 09:33
deleted any materials you were provided; correct? 09:33
A. No, I have not. 09:33
MS. LOCKARD: All right. This is a copy of 09:34
the materials considered list, which we'll mark as 09:34

Exhibit 3. 09:34
(Deposition Exhibit 3 was marked for identification and is attached hereto.) 09:34
MR. STANOCH: [Attorney indicates document]. 09:34
THE WITNESS: Oh. I am sorry. 09:34
BY MS. LOCKARD: 09:34
Q. Do you recognize that document? 09:34
A. I do. Yes. 09:34
Q. Did you prepare this yourself? 09:34
A. Actually, I had help from counsel to prepare the document. 09:34
Q. Who typed it up? 09:34
A. I -- I am not sure. 09:34
Q. Did you -- 09:34
A. But I -- sorry. 09:34
Q. Oh. Go ahead. 09:34
A. But it was provided for my review. 09:34
Q. Okay. Did you go through and compare what is on this list to what is actually in your electronic files? 09:34
A. Yes. I did an audit of that. I can't say that I looked at every single document to verify. 09:34
But, certainly, I took a look at it against what I was provided. 09:34
Q. I notice there are no -- there are no 09:35

references to literature publications on this list; is that correct? 09:35
MR. STANOCH: Objection. 09:35
Go ahead. 09:35
THE WITNESS: I would have to go through the list to see if there is a reference to specific literature or standards in the industry. 09:35
BY MS. LOCKARD: 09:35
Q. Okay. Go ahead and do that if you need to. 09:35
A. [Witness reviews document]. 09:36
No, there does not appear to be any literatures for a specific standard identified in the list. 09:36
Q. Okay. Did you review any literature publications or standards in connection with your -- generating your opinions in this case? 09:36
A. Certainly, I used general standards that are in the industry and would have had considered those in my normal practice and for this case. 09:36
Q. So would those be like the ICH standards and -- 09:36
A. Correct. 09:36
Q. Okay. And I understand some of that was cited in your report; right? 09:36

A. [Witness nods head up and down]. 09:36
Q. The standards that you refer to, the standards in the industry, were any of those provided to you by plaintiffs' counsel? 09:36
A. No. 09:36
Q. Okay. So all the standards -- industry standards, FDA rules, regulations, cGMPs guidances -- those were all things that you found yourself or were already aware of. 09:37
Is that fair? 09:37
A. Yes. That is fair. 09:37
Q. So did counsel at any time say, "Take a look at this. Here is a guidance. Here is a European guidance. Here is a, you know, new standard"? Anything like that that they actually provided to you? 09:37
A. No, ma'am. 09:37
Q. All right. If you looked at any standards -- cGMPs rules, regulations, or guidances -- in connection with your view of this case, then they are -- is it true to say they are cited or referenced in your report? 09:37
A. Yes, ma'am. 09:37
Q. Did you actually pull a set of those guidances and rules and cGMPs and look at them, read 09:37

them; or do you feel like you have a familiarity enough that you can sort of speak without actually pulling the document and reading it? 09:38
A. I would pull the document and read it. 09:38
Only in that I -- I don't have a memory -- or a memory of something like that. Certainly, I use these documents and standards on a routine basis in my practice, and I have access to these documents. 09:38
I would pull them and read them to make a reference. 09:38
Q. Or if we looked in your file in this case, would there be copies of those documents in your electronic file? 09:38
A. Not for this case. I keep guidances and regulations in separate electronic files in -- in my reference documents. 09:38
Q. Okay. On Exhibit 3, just to get some clarification on this if you want to follow along with me. 09:38
And let me ask: You know, if it's on this document, does it mean that you actually reviewed it or does it just mean that it was provided to you by counsel? 09:39
A. It was provided to me by counsel, certainly, if it's on the list. And I opened every document that was provided to me to see what it was. 09:39

Page 26

The extent to which I used it may differ, but certainly I opened every document. 09:39
Q. Okay. Were there things that you asked for to review from counsel that you did not receive? 09:39
A. Unless it was not provided in the production, there may have been some things that I asked for specifically that either I or counsel could not find in the production. 09:39
Q. Do you recall what those items were? 09:39
A. It would be specifically around raw data from testing. And what I mean by "raw data" is not summaries or certificates of analysis but the actual raw data and chromatograms. 09:40
Q. Were you requesting chromatograms from ZHP or from Teva or Torrent or someone else? 09:40
A. All of the above. 09:40
Q. Did you see any chromatograms in your production? 09:40
A. There were chromatograms that are associated with method validations, which are tests to validate whether a method is appropriate. But I was -- I didn't see chromatograms for raw testing batches that came from ZHP. From either ZHP or -- unless it was referenced in a report, I didn't just see the raw data for production batches. 09:40

Page 27

Q. So if -- if -- there may have been references to certain chromatograms that were included in investigation reports, for example. 09:40
You would have seen those? 09:41
A. Yes. Or a validation report. Yes. 09:41
Q. Okay. But you did not see any raw data containing chromatograms in anything that was provided to you? 09:41
MR. STANOCH: Objection to form. 09:41
Go ahead. 09:41
THE WITNESS: No. 09:41
BY MS. LOCKARD: 09:41
Q. So the initial set of materials here are pleadings. 09:41
Did you review these pleadings, the -- the Complaint? 09:41
A. Yes, ma'am. 09:41
Q. The -- the briefing on the class action? 09:41
A. Yes, ma'am. 09:41
Q. And then we have what is listed as "Declaration of Numerous Experts." 09:41
Now, are you referencing the expert reports here? 09:41
A. Yeah. These declarations are expert reports. 09:41

Page 28

Q. Okay. There are -- this is a -- this is a subset of the experts who have been identified in this case. 09:41
Were these just the expert reports that were provided to you by counsel? 09:41
A. Yes. 09:42
Q. Okay. 09:42
A. And they were germane to what I was opining on. 09:42
Q. All right. Do you -- I don't -- some of these experts have given multiple reports at various phases in the case. 09:42
Can we assume that you -- well, strike that. 09:42
Let me take, for example, so Dr. Baertschi. So he gave a report previously in the case and has given a subsequent report within the last month at the end of December. 09:42
Are you familiar with that? 09:42
A. Yes. 09:42
Q. Okay. Have you seen Dr. Baertschi's latest report? 09:42
A. I have. 09:42
Q. Okay. So there are things that are not on this list that need to be added. 09:42

Page 29

Is it fair? 09:42
A. They were not considered for my expert report. I have seen the document, but my expert report had been generated by that time. So I didn't consider those documents when writing my report. 09:42
Q. Sure. 09:43
MR. STANOCH: And I'll state for the record that, in our objections and responses to the notice of deposition, we identify the additional materials post Mr. Russ's report that he was provided with. 09:43
MS. LOCKARD: Yeah. I have a copy of that. 09:43
BY MS. LOCKARD: 09:43
Q. All right. On the original list there are numerous deposition transcripts, including company witnesses from several of the defendants. 09:43
Did you review each of these depositions in total? 09:43
A. I opened the documents, and I would say I scanned the documents. They are enormous. And, no, I didn't review each and every one in detail, necessarily. 09:43
Q. Okay. Do you recall any particular depositions that you read in full, if any? 09:43
A. Certainly the deposition -- I am sorry. 09:44
[Witness reviews document]. 09:44

Page 30

From Mr. Jaiswal from Torrent. Ms. Chitty 09:44
from Torrent I read in -- in full. I know those two 09:44
I have read in full. 09:44
Others I have read excerpts from. I can't 09:44
tell you the percentage of each of those that -- 09:44
that I have read. 09:44
Q. Were there any on this list that you 09:44
opened and decided they were not relevant for your 09:44
purposes and so -- 09:44
A. Yes. 09:44
Q. Which ones were those? 09:44
A. I can't recall that right now. 09:44
Q. Did you review any depositions of any of 09:44
the experts identified in the case? 09:44
A. If they are on this list, then they were 09:44
provided to me, and I opened them as a minimum. 09:44
Q. Okay. I only see declarations for the 09:44
experts. I don't see any expert depositions. 09:44
So in that case, we can assume you did not 09:45
read any of the expert depositions prior to your 09:45
report; right? 09:45
A. If it's not on this list, then I -- I did 09:45
not read it. Yes. 09:45
MS. LOCKARD: All right. I'll mark as 09:45
Exhibit 4 plaintiffs' counsel's objections and 09:45

Page 31

responses to defendants' notice of videotaped 09:45
deposition of Philip Russ. 09:45
BY MS. LOCKARD: 09:45
Q. I'll hand you a copy of that. 09:45
(Deposition Exhibit 4 was marked for 09:45
identification and is attached hereto.) 09:45
BY MS. LOCKARD: 09:45
Q. Have you seen this, Mr. Russ? 09:45
A. I have not. 09:45
MS. LOCKARD: Where is it -- where is it 09:45
listed? 09:45
Off the record for a second. 09:45
THE REPORTER: Off the record? 09:46
THE VIDEOGRAPHER: Okay. Going off record 09:46
at 9:46 a.m. 09:46
(Brief recess.) 09:46
THE VIDEOGRAPHER: And we are back on the 09:46
record at 9:47 a.m. 09:46
BY MS. LOCKARD: 09:46
Q. Okay. Mr. Russ, so have you seen this 09:47
document that is the objections? 09:47
A. No, I have not. 09:47
Q. Okay. So Counsel has represented that it 09:47
includes a listing of the additional materials you 09:47
have reviewed and considered since your report was 09:47

Page 32

generated at Page 10, if you'll take a look there. 09:47
A. [Witness reviews document]. 09:47
Yeah. This is correct. I was provided 09:47
these reports. But did not consider these reports 09:47
when generating my report. 09:47
Q. Having reviewed these reports since 09:47
generating your report, is there anything that you 09:47
need to change about your opinions? 09:47
A. No, ma'am. 09:47
Q. Okay. So in terms of the expert reports 09:47
that were provided here, did you request these or 09:47
were these just provided to you by counsel? 09:47
A. They were provided to me by counsel for 09:47
information purposes. 09:47
Q. All right. So in response to this 09:48
Number 12, in terms of the plaintiffs' expert 09:48
reports, it looks like you reviewed Dr. Hecht's 09:48
October report; correct? 09:48
A. Yes. 09:48
Q. And then the only defendants' reports you 09:48
have reviewed since generating your report would be 09:48
Dr. Williams, Mr. Anderson, and Dr. Baertschi, and 09:48
Dr. Nagaich? 09:48
A. Yes, ma'am. 09:48
Q. Is that right? 09:48

Page 33

Since generating your report, have you 09:48
reviewed any additional corporate documents? 09:48
A. Yes. 09:48
Q. Okay. What have you reviewed since 09:48
generating your report? 09:48
MR. STANOCH: Objection. Vague. Talk about 09:48
new documents that he hasn't reviewed before? Or... 09:48
MS. LOCKARD: Yes. Yes. Let's do that. 09:48
Let's start there. 09:48
MR. STANOCH: Okay. 09:48
BY MS. LOCKARD: 09:48
Q. Any additional documents that you had not 09:48
previously reviewed prior to your report, have you 09:49
now reviewed new documents or additional documents? 09:49
A. Yes. I was provided some documents that 09:49
were referenced in -- in defendant reports that were 09:49
not in the original production. 09:49
Q. Okay. What were those documents? 09:49
A. Some procedures, SOP references, standard 09:49
operating procedure references from Mr. -- I 09:49
apologize. I'm unable to reference his name -- from 09:49
Mr. Nagaich [verbatim]. 09:49
Q. Okay. 09:49
A. Some -- some items were referenced within 09:49
his report that had not -- did not have Bates 09:49

Page 34

numbers that were provided to me for review. 09:49
Q. Any other documents that you had not seen 09:49
before generating your report that you have now 09:50
since reviewed? 09:50
A. No. 09:50
Q. Have you reviewed, since generating your 09:50
report, any literature, any additional standards, 09:50
any additional -- extra material that would not be 09:50
either listed in your report or on your materials 09:50
considered list? 09:50
A. No, ma'am. 09:50
Q. If we look at your file, your electronic 09:50
file, is there anything else in it regarding this 09:50
case other than what we have already discussed that 09:50
is on this exhibit and what has been disclosed as -- 09:50
in the objections and the documents that you just 09:50
described about the SOPs? 09:50
A. No, ma'am. 09:50
Q. Did you take any handwritten notes in your 09:50
review of the case? 09:51
A. No, ma'am. 09:51
Q. Did you take any typed notes? Do you type 09:51
up notes? 09:51
A. Actually, no. 09:51
Q. Do you -- when you review the materials, 09:51

Page 35

do you annotate or highlight? 09:51
A. Actually, no. 09:51
Q. In connection with your review of the 09:51
case, have you spoken with anyone other than counsel 09:51
for the plaintiffs? 09:51
A. No, ma'am. 09:51
Q. Have you seen any -- well, strike that. 09:51
All right. Let's get a copy of your CV 09:52
marked as an exhibit. 09:52
MS. LOCKARD: This will be 5. 09:52
(Deposition Exhibit 5 was marked for 09:52
identification and is attached hereto.) 09:52
BY MS. LOCKARD: 09:53
Q. All right. Is that an up-to-date copy of 09:53
your CV, Mr. Russ? 09:53
A. It is. 09:53
Q. When is the last time you updated this? 09:53
A. I update my CV probably every four to 09:53
six months. 09:53
Q. Do you -- do you have different CVs that 09:53
you use for different purposes? 09:53
A. No, I don't. This is my standard 09:53
consulting CV. 09:53
Q. Your -- your education is not on your CV. 09:53
Why is that? 09:53

Page 36

A. It's not something I placed on my CV. 09:53
Q. What year did you get your degree? 09:53
A. 1995. 09:53
Q. Okay. And is the -- the BS degree from 09:53
1995, is that the only academic degree you hold? 09:54
A. It is. 09:54
Q. Have you ever held any teaching or 09:54
academic positions? 09:54
A. No, ma'am. 09:54
Q. So I noticed that your CV doesn't include 09:54
any articles, abstracts, or publications authored by 09:54
you; correct? 09:54
A. No, it doesn't. 09:54
Q. Have you not authored any publications or 09:54
literature in your field? 09:54
A. I have presentations and items like that, 09:54
but I don't include that type of information on my 09:54
CV. 09:54
Q. Have you -- are you published as an author 09:54
in any peer-reviewed literature journal? 09:54
A. No, I'm not. 09:54
Q. In terms of seminar presentations, I 09:54
assume you give seminar presentations to potential 09:54
clients that you are working with? 09:54
A. Yes. Or to -- not potential clients, but 09:55

Page 37

to clients who have asked for me to provide those 09:55
types of presentations. 09:55
Q. Have you ever provided any presentations 09:55
to the FDA or any other regulatory body? 09:55
A. I provided presentations in forums where 09:55
members of FDA have been present, but not at the 09:55
request of -- or the request -- I'm sorry -- of FDA 09:55
or any other regulatory body. 09:55
Q. Okay. In that context, have you provided 09:55
professional presentations at professional seminars 09:55
where FDA was present? 09:55
A. Yes. 09:55
Q. Okay. When is the last time you did that? 09:55
A. Quite a few years ago. I couldn't give 09:55
you a year. I used to be highly affiliated with 09:55
what is called the ISP and gave presentations at 09:55
that time in -- the same time that I was working for 09:56
Abbott Vascular on my CV would be a time that I was 09:56
involved with ISP. 09:56
But since then I haven't given many 09:56
presentations in public forum. 09:56
Q. What does "ISP" stand for? 09:56
A. It's the International Society of 09:56
Pharmaceutical Engineers. 09:56
Q. Okay. You are not an engineer; correct? 09:56

Page 38

A. No, I'm not. ISP is an organization -- an industry self-regulation where they provide guidance and training materials.
Although they are identified as an engineering group, they do a lot more than engineering.
Q. Why are you no longer affiliated with them?
A. It's not that I'm no longer affiliated with them. I just don't present in their -- in their forums any longer. I'm no longer a member.
When I worked for Abbott Vascular, I was required to provide presentations as part of -- just our presence as -- as a self-regulating company within the industry.
Q. Okay. So now that you no longer work at Abbott do you, in your present role, provide professional presentations as part of professional seminars?
A. I do most certainly, but I do that for pay. I do that for compensation.
Q. Okay. You no longer do that as part of your job for free?
A. Correct.
Q. All right. Are you a member of any

Page 39

professional organizations or bodies that are not listed on your CV?
A. Not currently, no.
Q. Have you ever given any presentations on the issues that are central to this case, such as, you know, the -- the detection of impurities in pharmaceutical products?
A. No.
Q. Have you ever given any presentations on issues related to nitrosamines?
A. No.
Q. Have you ever written any papers or publications about nitrosamines?
A. No.
Q. Have you ever had an occasion to perform work, either as a consultant or as an employee of a company, to evaluate raw data chromatograms for presence of what turned out to be nitrosamines?
A. No, not specifically for nitrosamines, but I certainly have reviewed chromatograms and raw data.
Q. So you -- you yourself have never been in the shoes of someone looking at a chromatogram in the raw data trying to determine whether that is a nitrosamine or not a nitrosamine?

Page 40

MR. STANOCH: Objection --
THE WITNESS: No.
MR. STANOCH: -- to form.
Go ahead.
BY MS. LOCKARD:
Q. When did you first learn about the issue with nitrosamines being present in pharmaceutical products?
MR. STANOCH: Objection. Vague.
THE WITNESS: Certainly when contacted by counsel. The only other occasion where I had some knowledge of that type of contamination was news reports around Zyrtec [verbatim].
BY MS. LOCKARD:
Q. Okay. Do you mean "Zantac"?
A. Or Zantac. I am sorry. Yes. I get --
Q. Okay. So did you see any publications from FDA or in the industry related to Valsartan-containing nitrosamines prior to being contacted by counsel?
A. I can't say that I did.
Q. You cannot say that you did?
A. I cannot say that I did.
I review an enormous amount of information that comes from FDA about enforcement actions about

Page 41

what is going on in the industry, but I can't say that, prior to being contacted by counsel to opine on this matter, that I can remember a time or date when I was specifically reading articles around Valsartan. Unfortunately, I can't retain all of that information.
Q. Okay. Even in your role as a -- in the quality assurance departments at your companies, you never recall hearing or seeing anything about the potential presence for nitrosamines, did you?
MR. STANOCH: Objection.
Go ahead.
THE WITNESS: As for this matter in -- in Valsartan? If you can clarify the question.
BY MS. LOCKARD:
Q. In your role in working in the quality assurance department in your prior employment, working for drug companies, you never heard or saw anything about the potential for the presence of nitrosamines in drug products, did you?
MR. STANOCH: Objection.
Go ahead.
THE WITNESS: I can't say that I -- I can't recall.
///

Page 42

BY MS. LOCKARD: 10:01
Q. Okay. You -- 10:01
A. Again, I have been consulting since 2008. 10:01
So that's quite a long time ago for me to recall 10:01
while I was working for a firm on whether there was 10:01
specific concerns around nitrosamines. 10:01
Q. Okay. But prior to 2008 when you were 10:01
working for drug companies, you don't recall ever 10:01
hearing anyone discuss the potential for the 10:01
presence of nitrosamines in the drug products; 10:01
right? 10:01
A. I -- I -- in my role did not hear that 10:02
specifically that I can recall. 10:02
Q. Since you have been an outside consultant, 10:02
have you ever had occasion to provide services to a 10:02
firm or a company with respect to investigating the 10:02
presence of nitrosamines? 10:02
A. Not specifically nitrosamines but 10:02
certainly other types of impurities that would occur 10:02
in drug products or drug substances. 10:02
Q. Okay. And so you would agree in -- 10:02
drug -- drug impurities are fairly common, and there 10:02
is a wide variety of them; correct? 10:02
MR. STANOCH: Objection to form. 10:02
THE WITNESS: Impurities are something that 10:02

Page 43

is evaluated in pharmaceuticals and in drug 10:02
substances. When I say "pharmaceuticals," I mean 10:02
finished drug products and drug substances. 10:02
So certainly impurities are a -- are 10:02
something that is evaluated. And there are some 10:02
levels of impurities that are present in -- in 10:02
pharmaceutical products and drug substances. 10:03
BY MS. LOCKARD: 10:03
Q. But in your role as a consultant, you have 10:03
never been hired by a company to help investigate 10:03
the potential for nitrosamine contamination. 10:03
Is that fair? 10:03
A. That is fair. 10:03
Q. When were you first contacted about this 10:03
case? 10:03
A. I think in the middle of last year. I 10:03
can't give exact date. Maybe the retention letter 10:03
would give us a better idea. I think the middle of 10:03
last year. I have quite a few clients. So... 10:03
MS. LOCKARD: All right. So we're up to 10:03
Exhibit 6. 10:03
So I'm just going to pass it over there to 10:03
mark. 10:04
(Deposition Exhibit 6 was marked for 10:04
identification and is attached hereto.) 10:04

Page 44

THE WITNESS: Thank you. 10:04
BY MS. LOCKARD: 10:04
Q. Okay. You mentioned -- 10:04
A. The middle. 10:04
Q. -- the "retention letter." 10:04
Is this what you meant by the "retention 10:04
letter"? 10:04
A. Yes, it is. 10:04
Q. Okay. And so the date on this is 10:04
June 16th, 2022; right? 10:04
A. Correct. 10:04
Q. Is that roughly the time around which you 10:04
were first contacted about the case? 10:04
A. It is. Mid-2022. 10:04
Q. All right. And the letter itself is -- is 10:04
from Conlee Whiteley and Ruben Honik at the -- do 10:04
you see that on the signature line? 10:04
A. Yes. 10:04
Q. Okay. Prior to being contacted about this 10:04
case, had you ever worked with Conlee Whiteley? 10:04
A. No. 10:04
Q. Okay. Prior to being contacted about this 10:04
case, had you ever worked with Ruben Honik? 10:04
A. No. 10:04
Q. Okay. Do you know how they got your name? 10:04

Page 45

A. I am not exactly sure of that as well. 10:04
Q. Do you advertise your expert witnessing 10:04
services? 10:05
A. No. Not -- not overtly. It's something 10:05
that is a capability that would be on my LinkedIn or 10:05
something along those lines. 10:05
My practice in general is a 10:05
word-of-mouth-type of referral business. I haven't 10:05
had the need to advertise my services. It's a very 10:05
small industry, and there is very small numbers of 10:05
people who do the type of work that we do. 10:05
Q. So are you, to your knowledge, on any 10:05
databases of experts that lawyers can consult when 10:05
they are looking for experts for litigation? 10:05
A. Not that I am aware of. Not specifically. 10:05
I haven't asked to be included on such lists. 10:05
Q. And do you -- you don't pay to be included 10:05
on the list? 10:05
A. No. I don't pay. 10:05
Q. Is -- do you -- do you have a website for 10:05
your company? 10:05
A. I have in the past. It's -- I've shut 10:05
this down because I don't receive any business 10:06
through it. 10:06
My main vehicle through which strangers, 10:06

Page 46

if you will, or a client who I have not worked with 10:06
in the past or who doesn't have a direct affiliation 10:06
or referral is through my LinkedIn. 10:06
Q. I wanted to ask too. So your company is 10:06
IcGXP; correct? 10:06
A. Correct. 10:06
Q. What does that stand for? 10:06
A. It's Innovative consultants GXP. So the 10:06
industry calls the regulations -- the regulations 10:06
are called the "Current Good Manufacturing 10:06
Practice." But across there are other practices. 10:06
There is "Good Clinical Practice." There is "Good 10:06
Laboratory Practice." So the "X" stands for that 10:06
"Manufacturing, Laboratory, Clinical." So that's 10:06
why the "X" is there. 10:07
Really just shows in the name of the 10:07
company what my capability or what my expertise is, 10:07
which is in GXP matters. 10:07
Q. So how long has that been the name of your 10:07
company? 10:07
A. Since its inception -- 10:07
Q. 2008. 10:07
A. -- in 2008. 10:07
Q. Did you come up with that name yourself? 10:07
A. I did. 10:07

Page 47

Q. Do you have any employees? 10:07
A. No. I don't have direct employees. But I 10:07
use colleagues who work with me routinely who are 10:07
paid on a 1099 basis. 10:07
Q. Okay. Did you use any of those colleagues 10:07
in this case? 10:07
A. I did. 10:07
Q. Okay. And would any time they spent be 10:07
reflected on your invoices? 10:07
A. It is. 10:07
Q. Okay. So no one else that you paid or 10:07
worked with assisted you on your review of this case 10:07
other than those reflected in the invoice; right? 10:07
A. Yes. 10:07
Q. Okay. And you are listed as a principal 10:07
consultant for your company; correct? 10:07
A. Yes. 10:07
Q. And you are the principal and the only 10:07
consultant for your company; correct? 10:08
A. Correct. 10:08
Q. Okay. So in looking back at the exhibit, 10:08
when you were first contacted -- let me ask too: 10:08
Because Mr. David Stanoch is here 10:08
defending your deposition today. Had you ever 10:08
worked with Mr. Stanoch before being contacted about 10:08

Page 48

this case? 10:08
A. No. 10:08
Q. Okay. Do you know any of the other 10:08
plaintiffs' lawyers who are involved in this case 10:08
other than those three names I have mentioned? 10:08
A. No. 10:08
Q. Okay. So have you met with anyone, any 10:08
plaintiffs' lawyers in this case other than 10:08
Mr. Stanoch? 10:08
A. Yes. 10:08
Q. Who else have you met with? 10:08
THE WITNESS: You'll have to help me, David. 10:08
Daniel, Mr. -- 10:08
MR. STANOCH: Whatever you remember. 10:08
THE WITNESS: Daniel; Madeline, I think. 10:08
And that's all I can recall. 10:09
BY MS. LOCKARD: 10:09
Q. Okay. And Madeline is with Daniel's firm; 10:09
correct? Or do you know that? 10:09
A. I am not completely sure the affiliations. 10:09
Q. All right. When did you -- let's take it 10:09
this way: 10:09
So we'll start off -- when you were first 10:09
contacted, did you get a phone call, LinkedIn 10:09
message, or how did you -- 10:09

Page 49

A. A phone message that I responded to. 10:09
Q. Who -- who left the message? 10:09
A. I think it was Mr. Hon- -- Mr. Honik -- 10:09
Q. Okay. 10:09
A. -- was my original contact. 10:09
Q. Okay. How -- how much time elapsed 10:09
between your original contact and this June 16th 10:09
letter? 10:09
A. I don't recall the exact number of days. 10:09
I would say maybe a week or so. 10:09
Q. Okay. And so you -- your first contact 10:10
was from a phone call from Mr. Honik; correct? 10:10
A. Correct. 10:10
Q. And how long was that phone call? 10:10
A. It wasn't a phone call. It was a message 10:10
that was left on my voicemail. And then I responded 10:10
to that call. 10:10
Q. All right. And did you call and speak 10:10
with Mr. Honik? 10:10
A. I did. 10:10
Q. Okay. How long was that conversation? 10:10
A. I don't recall. It was brief. 10:10
Q. Okay. What did he tell you? 10:10
MR. STANOCH: Object -- 10:10
THE WITNESS: I didn't say -- 10:10

Page 50

MR. STANOCH: -- objection. 10:10
You are asking for attorney discussions with 10:10
an expert. So... 10:10
BY MS. LOCKARD: 10:10
Q. Well, I -- I would like to know what did 10:10
he present to you about the facts of the case? How 10:10
about that? 10:10
MR. STANOCH: Same objection. 10:10
You are asking what Mr. Honik said to our 10:10
retained expert. 10:10
MS. LOCKARD: Well, he's not a client. I 10:10
mean, there's not an attorney-client privilege. I 10:10
can't get into work, you know, product. But -- 10:10
MR. STANOCH: Right. What -- what was said 10:10
between counsel and retained expert is work product. 10:10
Objection. 10:10
MS. LOCKARD: Well, I disagree with that. 10:11
If there were discussion about facts, documents, and 10:11
things of that nature that are not reflective of work 10:11
product and strategic considerations, I disagree. 10:11
But... 10:11
MR. STANOCH: Mr. Russ, if you can discuss 10:11
anything you may remember you discussed with Mr. Honik 10:11
that does not reveal substance about the potential 10:11
opinion you would offer in this case. 10:11

Page 51

THE WITNESS: Okay. 10:11
Certainly I had a conversation that "Would 10:11
you be interested in a matter that dealt with GMP? 10:11
"Yes, sir. I would be interested in that 10:11
matter." 10:11
And then retention occurred. 10:11
And then they would have disclosed to me 10:11
information. 10:11
But on initial calls with any client, 10:11
whether it be for a legal matter or for anything else, 10:11
in the absence of a non-disclosure agreement, I don't 10:11
have any discussions on details of the matter. 10:11
"Would you be interested? Do you have time 10:11
on your calendar to -- to look at this" is the extent 10:12
of those types of conversations. 10:12
BY MS. LOCKARD: 10:12
Q. Did he tell you who the defendants were? 10:12
A. No. I wouldn't have asked such a thing 10:12
either. 10:12
Q. Okay. Did he talk about any of the 10:12
defendants being foreign defendants, Chinese 10:12
manufacturer, or anything like that? 10:12
A. No. 10:12
Q. What -- on that call, I assume you told 10:12
him you would be interested, you had time; correct? 10:12

Page 52

A. Exactly. 10:12
Q. What was the next step? Did he send you 10:12
materials? You got this letter from Mr. Honik? 10:12
A. To be retained. Certainly to be retained, 10:12
and then any disclosure of documents or any further 10:12
information would be all under some non-disclosure. 10:12
Certainly I was informed of protective 10:12
order whether signed it or not is -- you know, I 10:12
have done this type of work before. I don't work 10:12
with any client without a non-disclosure agreement. 10:12
Q. Okay. And when you say "non-disclosure," 10:12
do you mean one that you generate and send to 10:13
counsel? 10:13
A. In legal matters, normally I don't 10:13
generate one. 10:13
It depends on the clients. Some clients 10:13
have non-disclosure agreements that are in their 10:13
corporate or legal format that they want me to sign. 10:13
In the absence of that, I do have 10:13
non-disclosure agreements -- two-way or one-way 10:13
non-disclosure agreements that I will send to a 10:13
client. But I don't work without a non-disclosure 10:13
agreement. 10:13
Q. So -- 10:13
A. Even -- even prior to signing the 10:13

Page 53

retention or with a client -- not necessarily, 10:13
again, in the legal side of things, but before an 10:13
agreement is put in place or before I can estimate a 10:13
job, I'll have a non-disclosure agreement in place. 10:13
Q. Did you sign a non-disclosure in this 10:13
case? 10:13
A. No. As I said, I don't normally do 10:13
non-disclosures because there is normally a 10:13
protective order or something along those lines in 10:13
those matters. 10:13
Q. Okay. The letter that you have that you 10:13
received on June 16th that sets forth your fees 10:14
here? 10:14
A. Yes. 10:14
Q. Okay. And is that -- 350, 400, are those 10:14
still the fees that you charge today? 10:14
A. It is. 10:14
Q. Do you charge the same amount for 10:14
testimony at trial? 10:14
A. I haven't listed that here. 10:14
Q. Okay. Have you testified at trial before? 10:14
A. I have not. 10:14
Q. Okay. What are you charging for your 10:14
attendance here today? 10:14
A. 400 would be for an in-person deposition 10:14

Page 54

services. 10:14
Q. All right. Now, when you received this 10:14
letter, did -- did you also receive the initial set 10:14
of materials for review at that time? 10:14
A. This -- no. After I would have -- after 10:14
we would have agreed to this letter, then I would 10:14
have received materials. 10:14
Q. Okay. Did you receive the materials 10:14
listed on your materials considered list all in one 10:14
production or did it come in different pieces? 10:15
A. I think the vast majority of it was 10:15
provided upfront, but there were other pieces as 10:15
well over the period of time. 10:15
Q. And when those materials were sent to you, 10:15
were they -- were they sent via email, an email 10:15
link? 10:15
A. It was done through Dropbox, share file. 10:15
I believe it's Dropbox. 10:15
Q. All right. So when did you have the 10:15
meeting with Mr. Nigh? 10:15
A. I'm sorry. Mr. Nigh? 10:15
Q. Daniel Nigh and Madeline? 10:15
A. Oh. I have had a couple of meetings. 10:15
These would be over the last -- since June. Maybe 10:15
twice I have had discussions. I can't give you the 10:15

Page 55

exact dates of those meetings. 10:15
Q. And those were in person or over Zoom? 10:15
A. Over Zoom. 10:15
Q. All right. Tell me about the process for 10:16
drafting your report. Did you do that in the 10:16
presence of counsel, or did you do that on your own 10:16
and then share drafts? 10:16
A. Completely on my own and then share 10:16
drafts. 10:16
Q. Okay. The report that you generated in 10:16
this case, is it your work that you actually drafted 10:16
and typed? 10:16
A. Yes. 10:16
Q. Do you have a template that you use for 10:16
your reports? 10:16
A. No. 10:16
Q. All right. Have you met with Mr. Stanoch 10:16
prior to this deposition today? 10:16
A. Yes. 10:16
Q. You met to prepare for your deposition? 10:16
A. Uh, yes. 10:16
Q. Okay. How long did you meet with 10:16
Mr. Stanoch? 10:17
A. A couple of hours. 10:17
Q. When was that? 10:17

Page 56

A. Yesterday. 10:17
Q. Did you have any phone conversations to 10:17
prepare? 10:17
A. Previously, yes. An hour conversation 10:17
twice before, previous weeks in December. 10:17
Q. With Mr. Stanoch? 10:17
A. Correct. 10:17
Q. What did you do to prepare for your 10:17
deposition other than meeting and discussing the 10:17
case with counsel? 10:17
A. I read my own report to refresh my memory. 10:17
Q. When is the last time you read your 10:17
report? 10:17
A. The 29th of December, I think. 10:17
Q. Okay. And in reviewing the report, did 10:17
you see any changes that you thought needed to be 10:17
made? 10:17
A. No, ma'am. 10:17
Q. Okay. So your report as it is, you stand 10:17
by it today? 10:17
A. I do. 10:17
Q. Do you anticipate making any changes or 10:17
supplements to that prior to trial? 10:17
A. Not at this time. No. 10:17
Q. Okay. Other than reading your report, 10:17

Page 57

what else did you do to prepare for today? 10:17
A. I had the meetings I have described. 10:18
Q. On your CV, just looking at your -- your 10:18
job positions, there's a reference to working at 10:18
Watson Laboratories? 10:18
A. Yes. 10:18
Q. From October 2000 to 2006; correct? 10:18
A. Yes. 10:18
Q. What did you do for Watson? 10:18
A. Initially, I had two positions at Watson. 10:18
The first was to support the manufacturing 10:18
facility in Corona, California, as -- to support the 10:18
quality system there. 10:18
So my job was to oversee the GMP 10:18
compliance and quality system at the site. 10:19
And then subsequently I went to work for 10:19
corporate Watson, which was also in Corona, 10:19
California. And at that time I had responsibility 10:19
for their contract manufacturing organization, the 10:19
quality oversight of contract manufacturing and 10:19
suppliers for Watson -- 10:19
Q. Why did -- 10:19
A. -- as a -- as a corporation. I'm sorry. 10:19
Q. Okay. When you had oversight at the 10:19
manufacturing site in Corona, what was manufactured 10:19

Page 58

there? 10:19
A. They manufactured two main product 10:19
categories: birth control and hydrocodone/APAP 10:19
combinations, which is a pain management, Vicodin, 10:19
generic Vicodin, if you will. 10:19
Q. Why did you leave Watson? 10:19
A. I primarily left Watson from a location 10:19
perspective. 10:20
I lived in Murrieta, California, which is 10:20
near Temecula, California. And just the commute was 10:20
very, very long. And I decided that from a 10:20
work-life balance perspective it made more sense for 10:20
me to work more local to my home. 10:20
Q. When you were at Watson, it was completely 10:20
unaffiliated with Teva at that time; correct? 10:20
A. Correct. 10:20
Q. And do you have any understanding about 10:20
the affiliation between Watson and Actavis and Teva? 10:20
A. Only in that I know about the 10:20
acquisitions. But I was not working with any of 10:20
those companies. So I knew about it from industry 10:20
that Watson was taken over by Actavis. That Actavis 10:20
was ultimately absorbed by Teva. I knew people, 10:20
certainly, who worked at Watson or at Actavis. 10:20
Q. To your knowledge, did Watson hold any 10:21

Page 59

approved ANDAs for Valsartan when you worked there? 10:21
A. Not for the Corona facility. No. 10:21
Q. What about from a corporate perspective? 10:21
A. Not that I was responsible for. No. 10:21
Q. Okay. Do you have an understanding of 10:21
when Watson submitted the ANDA to FDA for Valsartan? 10:21
A. It's in my report; so I understand it from 10:21
that perspective. 10:21
Q. Without looking at your report, do you 10:21
recall the time frame for that? 10:21
A. No. 10:21
Q. Okay. So there's a reference in your 10:21
report about the approval of the ANDA. But the 10:21
submission of the ANDA for Watson, I believe, was in 10:21
2008. And then -- and you left Watson in 2006? 10:21
A. Correct. 10:22
Q. Okay. So there would -- to your 10:22
knowledge, there would not have been -- would not 10:22
likely have been any overlap in Watson preparing for 10:22
submission of that ANDA in your tenure at Watson. 10:22
Is that fair? 10:22
A. That is -- that is fair. Yes. There 10:22
would be no overlap. I also have no responsibility 10:22
for the regulatory application submission. It 10:22
wasn't my role. 10:22

Page 60

Q. Okay. And that's really true for all of 10:22
your employment; correct? You have never really had 10:22
a role in the preparation and submission of the 10:22
regulatory applications for drugs? 10:22
A. I would be involved in the preparation of 10:22
what is called the CMC section, the Chemistry, 10:22
Manufacturing, Control Section, but as far as 10:22
management of the application or dates of 10:22
application, that was -- that is done by regulatory 10:22
affairs. 10:22
So I would provide information that would 10:22
go into a regulatory application, specifically the 10:22
CMC. 10:22
Q. But you have never been responsible for 10:22
preparing and submitting an ANDA or an NDA yourself? 10:22
A. As a whole, no. 10:23
Q. Okay. And the same would be -- you would 10:23
not have any role in your prior jobs in preparing a 10:23
CBE, or Changes Being Effected, and submitted to 10:23
FDA? 10:23
A. The submission I wouldn't do. But the 10:23
source information I would provide to regulatory 10:23
affairs. 10:23
Q. So for any quality source information you 10:23
would provide an input on that? 10:23

Page 61

A. Quality. Chemistry. Yes. 10:23
Q. Have you ever been terminated from any 10:23
position? 10:23
A. No. 10:23
Q. And I guess I should ask as well. 10:23
But you -- in your role in quality, it 10:23
would not have been your function or role to prepare 10:23
the submission of a DMF? 10:23
A. No. I have not worked for a drug 10:24
substance manufacturer directly, where I would have 10:24
been involved in submission of the DMF. 10:24
Q. Have you ever served on any committees or 10:24
been involved with any bodies that handled the 10:24
drafting of standards or guidances in your field? 10:24
A. No. 10:24
Q. And I don't see on your CV any particular 10:24
awards or accolades in your field; correct? 10:24
A. No. 10:24
Q. Is there -- I mean, is there -- you know, 10:24
any award or particular professional moment that you 10:24
are particularly proud of? 10:25
A. Not that I can state here. No. 10:25
Q. Okay. Is there anything else that -- with 10:25
respect to your professional qualifications, 10:25
experience, and background that is not on your CV? 10:25

Page 62

A. No. 10:25
Q. You are not a toxicologist; correct? 10:25
A. No. 10:25
Q. Okay. You are not an expert on the 10:25
potential health effects of nitrosamines; correct? 10:25
A. No. 10:25
Q. And I assume you are not planning to offer 10:25
any opinions about whether nitrosamines cause human 10:25
cancer in this case? 10:25
A. No. 10:25
Q. And you are not an expert on 10:25
bioequivalency or bioequivalence? 10:25
A. I'm not. 10:25
Q. In other words, you don't do 10:25
bioequivalence testing yourself? 10:26
A. No. 10:26
Q. And the same for therapeutic equivalence. 10:26
You don't consider yourself an expert in therapeutic 10:26
equivalence; you don't do testing for therapeutic 10:26
equivalence purposes? 10:26
A. No. 10:26
Q. That's correct? 10:26
A. That is correct. 10:26
Q. Let's get the -- your invoices marked as 10:27
the next exhibit. 10:27

Page 63

MS. LOCKARD: What are we at? 6? 10:27
MR. HARKINS: 7. 10:27
(Deposition Exhibit 7 was marked for 10:27
identification and is attached hereto.) 10:27
BY MS. LOCKARD: 10:27
Q. Okay. Mr. Russ, if you'll take a look at 10:27
what has been handed to you as Exhibit 7. 10:27
Does this appears -- 10:27
MR. STANOCH: Do you have a copy, Counsel? 10:27
MS. LOCKARD: Oh. Yes. Sorry. 10:27
MR. STANOCH: It's okay. Thank you. 10:27
BY MS. LOCKARD: 10:27
Q. I assume you have seen these? 10:27
A. Yes. 10:27
MS. LOCKARD: And Mr. Stanoch has. 10:27
BY MS. LOCKARD: 10:27
Q. So what I was provided in the production 10:27
from Mr. Stanoch was that they are -- it looks like 10:28
three invoices; correct? 10:28
A. Correct. 10:28
Q. Okay. To your knowledge, are these the 10:28
only invoices you've issued to date? 10:28
A. It is. Yes. 10:28
Q. All right. So there is a reference in 10:28
these invoices to a Sharon Crook? 10:28

Page 64

A. Correct. 10:28
Q. Who is Sharon Crook? 10:28
A. Sharon Crook is a colleague I used to help 10:28
me with sorting of the production. 10:28
Q. What is her background? 10:28
A. Very similar to mine. As she is -- has a 10:28
deeper background in validation engineering, but a 10:28
GMP compliance consultant, management consultant. 10:28
So very similar to myself. 10:28
Q. Is she -- you pay her as a 1099 for help? 10:28
A. I did. 10:28
Q. So when you say "sorting the production," 10:28
what do you mean by that? 10:28
A. Pulling the production, opening the 10:29
documents, making me aware of what documents are 10:29
available within the production. 10:29
She helped me to -- to sort documents as 10:29
they come through. There are an enormous number of 10:29
documents, reports, procedures, emails. Mostly 10:29
initially that type of triage. 10:29
Also to review expert reports that were 10:29
supplied or declarations -- I'm sorry -- that were 10:29
supplied. 10:29
Q. Did she, to your knowledge, have any 10:29
discussions directly with counsel? 10:29

Page 65

A. No. 10:29
Q. So where it says "Quantity" on the 10:29
invoices, that's hours? 10:29
A. Correct. 10:29
Q. Did Sharon Crook participate in drafting 10:29
any portion of your report? 10:29
A. No. 10:29
Q. Did she review your report and provide 10:29
input, edits, feedback? 10:29
A. No. 10:29
Q. On the first invoice, Page 2, it 10:30
references the June 30 and July 12th client 10:30
meetings. 10:30
Are those the meetings that you would have 10:30
had with Daniel Nigh? 10:30
A. I am -- again, would have to look at the 10:30
attendees' list on those meetings. In July, I -- I 10:30
would have to look at the attendees' list. 10:30
Again, twice. I think I have met with 10:30
Daniel twice. 10:30
Q. Okay. When you say the "attendees' list," 10:30
what do you mean? 10:30
A. Who was invited to the Zoom. That's what 10:30
I mean by the "attendees' list." 10:30
Q. Like on a calendar invite? 10:30

Page 66

A. A calendar invite. 10:30
Q. All right. So the first invoice itself, 10:31
it references the Quick report, the Quick 10:31
declaration and exhibits. 10:31
A. Yes. 10:31
Q. And the Anderson report with exhibits? 10:31
A. Yes. 10:31
Q. And the Baertschi report with exhibits; 10:31
And then the Williams report with 10:31
exhibits; 10:31
And then it says "Torrent R. Williams 10:31
report" on the last page, last entry. 10:31
Was that a Torrent expert report or was 10:31
that the report of Kevin's expert, Williams? 10:31
A. It -- Mr. Williams, whoever he was 10:31
representing, from a declaration. This may be a 10:31
typo. I'm not sure. 10:31
This is a timesheet from Sharon. She may 10:31
have made a mistake there. I'm not sure. 10:32
Q. Okay. On the second invoice itself -- in 10:32
the first invoice it's for $30,800; correct? 10:32
A. Yes. 10:32
Q. And then the second invoice is dated 10:32
September 29th, 2022, and that's for 31,400; 10:32
correct? 10:32

Page 67

A. Correct. 10:32
Q. And the third invoice is dated 10:32
November 1st, 2022, and that's for 16,100; right? 10:32
A. Correct. 10:32
Q. And so if I do the math insofar in total 10:32
it looks like you have billed $78,300? 10:32
A. Yes. 10:32
Q. All right. On the second invoice, there's 10:32
no, you know, detail -- task detail attached. 10:33
Why is that? 10:33
A. I think I just didn't add timesheets 10:33
because I was able to describe what was done 10:33
adequately in the description. 10:33
Q. But it says you have 69 hours? 10:33
A. Oh. I see attached timesheets. 10:33
Q. And there is no accounting for what was 10:33
done on the 69 hours. I wish I could get away with 10:33
that with my clients. But... 10:33
MR. STANOCH: Well, objection. It's a time 10:33
entry describing what was done. So I'm not sure what 10:33
you are getting at. 10:33
Objection. 10:33
BY MS. LOCKARD: 10:33
Q. Okay. So do you think there are 10:33
timesheets that would reflect what was done for this 10:33

Page 68

29 hours but they just haven't been produced? 10:33
A. I'm not sure. I would have to actually 10:33
look. I, again, work with a lot of clients. The 10:33
details of the invoice I would have to go look. I'm 10:33
not sure. 10:33
Q. Okay. And the second -- excuse me. 10:34
Sorry. Strike that. 10:34
The third invoice, it's for 46 hours, and 10:34
then it does have the timesheet task detail 10:34
attached. 10:34
A. Right. 10:34
Q. And it describes primarily review of -- of 10:34
preparation of the draft report and meeting with the 10:34
client. 10:34
A. Yes. 10:34
Q. So it appears from this -- it looks like 10:34
the bulk of the materials that you would have 10:34
reviewed that are listed on your materials 10:35
considered list would have been reviewed in the 10:35
69-hour time period because they are not listed on 10:35
any other invoice. 10:35
MR. STANOCH: Objection to form. Every 10:35
invoice states "Document Review." So misrepresents 10:35
the documents. 10:35
THE WITNESS: They all three represent -- 10:35

Page 69

there was certainly document review across... 10:35
"Document review. 10:35
"Document review. 10:35
"Document review." 10:35
BY MS. LOCKARD: 10:35
Q. How many more hours do you think you have 10:35
spent on this case since this third invoice was sent 10:35
in November? 10:35
A. Maybe 25 hours. 30 hours, maybe. 10:35
Q. And have your invoices all been paid to 10:35
date? 10:35
A. I haven't submitted a December invoice. 10:35
Only in that the holidays got to me, I think. And 10:35
certainly the deposition has been scheduled this 10:36
first week, I figured I would just get all of that 10:36
work on one invoice to the client. 10:36
Q. But -- 10:36
A. Including the deposition. 10:36
Q. But -- but you have -- you have had no 10:36
problem getting paid for the invoices you sent; 10:36
correct? 10:36
A. Oh, no. No. Yes. I have been paid 10:36
timely, certainly. 10:36
Q. On your CV itself, you reference some of 10:36
your clients on Page 1. 10:36

Page 70

Do you see that? 10:36
A. Yes. 10:36
Q. And on there I saw reference to Teva. 10:36
A. Yes. 10:36
Q. Okay. What have you done in your 10:36
consulting role for Teva? 10:36
A. For Teva, I have worked on an audit -- 10:37
what is called an audit readiness plan for their 10:37
parenteral manufacturing facility in Irvine, 10:37
California. 10:37
Q. Okay. So that was for the parenteral 10:37
manufacturing facility out in Irvine? 10:37
A. Correct. 10:37
Q. Okay. How long ago was that? 10:37
A. At least ten years. 10:37
Q. Okay. Did you work on -- have you worked 10:37
on any other projects for Teva? 10:37
A. No. That's the only project I have worked 10:37
on for Teva. 10:37
Q. And how long did your project for Teva 10:37
last for the Irvine plant? 10:37
A. A couple of months, I would say. 10:37
Q. Do you recall who you worked with, who 10:37
your contact was? 10:37
A. A gentleman by the name of Kevin Charrier. 10:37

Page 71

Q. Do you know if he still works at Teva? 10:38
A. Not that I am aware of. 10:38
Q. That facility has shut down, I believe. 10:38
Is that your understanding? 10:38
A. It is. Yeah. 10:38
Q. Okay. Is that the one and only time you 10:38
have been hired by Teva as a consultant that you 10:38
recall? 10:38
A. It is. 10:38
Q. In looking through the -- the pleadings 10:38
and seeing the defendants that are involved in this 10:38
case, did you -- did you see any other named 10:38
defendants that you have done consulting work for? 10:38
A. No. 10:38
Q. So you haven't done work for ZHP or 10:38
Prinston or Solco? 10:38
A. I have not. 10:38
Q. And you have not done any consulting work 10:38
for Torrent? 10:38
A. No, I have not. 10:38
Q. And no consulting work for Hetero or 10:38
Aurobindo? 10:38
A. No, I have not. 10:38
Q. Okay. And no consulting for Mylan? 10:38
A. No, I have not. 10:38

Page 72

MS. LOCKARD: Okay. We have been going 10:39
about an hour. So let's take just a quick break for 10:39
everyone and the court reporter. 10:39
MR. STANOCH: Sure. 10:39
10:39 THE VIDEOGRAPHER: Okay. Going off record 10:39
10:39 at a.m.
(Brief recess.) 10:39
THE VIDEOGRAPHER: And we are back on the 10:41
10:52
10:52 record at a.m. Start of
Media Number 4.
MS. LOCKARD: Okay. Let's get this marked 10:52
as Exhibit 8, please. This will be the report of 10:52
Philip Russ. 10:52
(Deposition Exhibit 8 was marked for 10:52
identification and is attached hereto.) 10:52
MS. LOCKARD: Do you need a copy of it? 10:52
MR. STANOCH: I am -- I am good. I have it. 10:52
Thank you, Counsel. 10:52
MS. LOCKARD: Okay. 10:52
MR. STANOCH: Thank you. 10:52
MS. LOCKARD: I'll just give -- I will just 10:52
give you your own copy. 10:52
Just a second. 10:52
BY MS. LOCKARD: 10:53
Q. All right, Mr. Russ. So let's talk a 10:53
little bit about the report you submitted. 10:53

Page 73

This report was submitted with opinions 10:53
about Teva and Torrent. Primarily my focus will be 10:53
about Teva. 10:53
You may get questions, and I'm sure you 10:53
will, from Torrent's counsel a little bit later 10:53
today. And so those questions will probably focus 10:53
on Torrent. 10:53
But to the extent your responses apply 10:53
generally to somewhat general questions, certainly 10:53
you don't need to be too concerned about -- about 10:54
that. 10:54
The one thing that it looks like on your 10:54
testimonial history, there was -- I think in the 10:54
objections and responses, there was an addition 10:54
provided related to a more recent testimony or 10:54
expert report you had given in another case. 10:54
Does that ring a bell? 10:54
A. I am -- I am sorry. No. I don't -- it 10:54
doesn't ring a bell. But what specifically are 10:54
you... 10:54
Q. Well, we'll -- I'll come back to that in a 10:54
few minutes. 10:54
Okay. So going through your report here 10:54
it appears to me that your -- your criticisms 10:54
against Teva really fall into sort of two 10:54

Page 74

categories. One relates to the oversight and 10:54
management of the supply relationship with ZHP, and 10:54
the other seems to relate to the handling of the 10:54
recall and the hold and the notification to FDA. 10:55
So is that fair if we sort of deal with 10:55
them in two buckets? 10:55
MR. STANOCH: Objection to form. 10:55
But go ahead. 10:55
THE WITNESS: Yes. That seems fair. 10:55
BY MS. LOCKARD: 10:55
Q. So in -- in terms of the -- there's a lot 10:55
of background information in here with respect to 10:55
how the drug approval process works and submissions 10:55
of ANDAs by generic drug manufacturers and that sort 10:55
of thing. 10:55
And so some of the things I want to go 10:55
through with you are just to try to discern whether 10:55
they are intended to be criticisms or whether it's 10:55
just background information. Okay? 10:55
A. Okay. 10:55
Q. So there's a reference in Paragraph 14 10:55
about -- if you turn with me to Page 3. 10:55
[As read]: 10:55
"FDA approval is also required for 10:55
generic drugs, however, generics do not 10:55

Page 75

need to include all the preclinical and 10:55
clinical research steps to establish 10:56
safety the way brand-name products do 10:56
for NDAs." 10:56
That's your statement; right? 10:56
A. It is. 10:56
Q. Okay. So you are not in any way 10:56
criticizing the generics for failing to do a 10:56
preclinical or clinical research steps on their own 10:56
in this case? 10:56
A. No. 10:56
Q. That's perfectly allowable under the rules 10:56
and regulations of the FDA; correct? 10:56
A. Absolutely. 10:56
Q. Okay. So do you have any criticisms of 10:56
Teva with respect to the submission of their ANDAs 10:56
in this case? 10:56
A. No. 10:56
Q. On Paragraph 23 there's a reference to the 10:56
reason for the process change at ZHP. 10:57
Do you see that? 10:57
A. I do. 10:57
Q. And the -- the reason that you provided 10:57
here states [as read]: 10:57
"ZHP identified the change would 10:57

Page 76

double production scale while at the 10:57
same time reducing racemization and 10:57
generation of impurity." 10:57
Do you see that? 10:57
A. I do. 10:57
Q. Okay. On -- there's a citation to 10:57
PRINSTON73102, that document? 10:57
A. Yes. 10:57
MS. LOCKARD: Do we have a copy of that 10:57
document? 10:57
BY MS. LOCKARD: 10:57
Q. Just in terms of your understanding as to 10:57
why that change was made, what -- what is your 10:57
understanding of why ZHP made the process change? 10:57
A. I just restated what was in -- what they 10:57
described in the document. 10:57
Q. All right. Did you find that to be a 10:57
reasonable justification for the change? 10:58
MR. STANOCH: Objection to form. 10:58
THE WITNESS: I had no feelings on it either 10:58
way. 10:58
BY MS. LOCKARD: 10:58
Q. But that -- the justification that is 10:58
provided is -- is within the realm of a reasonable 10:58
or prudent justification for making process change? 10:58

Page 77

MR. STANOCH: Objection to form. 10:58
THE WITNESS: Again, that's -- it doesn't 10:58
appear to me to be a red flag in some way. But that 10:58
would be an evaluation that ZHP would perform. I 10:58
didn't have all of the data I would need to determine 10:58
whether that was reasonable or appropriate. 10:58
BY MS. LOCKARD: 10:58
Q. In -- in terms of the -- the statement 10:58
that is here, the actual statement that is in the 10:58
Prinston document itself relates to generation of 10:58
impurity A, not just all impurities. 10:58
Do you recall that? 10:58
A. I could look at the document and 10:58
acknowledge if that's the case. 10:59
Q. Okay. We may pull that up. We are 10:59
looking for it. And I'll -- I'll come back to that. 10:59
There was also a reference in the document 10:59
to, quote, "EHS concern." 10:59
Do you know what that meant or what that 10:59
was in reference to as a -- as another reason for 10:59
the change? 10:59
A. "EHS" is "Environment Health and Safety." 10:59
So a safety concern to keep manufacturing operators 10:59
more safe in the manufacture of the product. 10:59
Q. Okay. So you understood that one of the 10:59

Page 78

justifications for the change from ZHP's documents, at least, was in order to reduce health and safety concerns for its workers; correct? 10:59

MR. STANOCH: Objection to form. 10:59

THE WITNESS: If the document states that, then, yes, I acknowledge that. 10:59

BY MS. LOCKARD: 11:00

Q. There are some references as well on Paragraph 24 that relates to Teva's purchase of Valsartan API for Mylan. 11:00

Do you see that? 11:00

A. I do. 11:00

Q. Why did you include that in this report if this case is focused on the ZHP product? 11:00

A. I included it because it's germane to how they handled their post-notification investigations. 11:00

Q. You understand that in the trial that we are preparing for in this case and for which your deposition is being given, the Mylan product, the Mylan API is not at issue? 11:00

A. I understand that. But I added it because of Teva's handling of the overall investigation for Valsartan materials that they were using. 11:00

Q. Okay. And, in fact, you included a reservation in your report that -- that you would 11:01

Page 79

reserve opinions with respect to Teva and Mylan's API for a later date; correct? 11:01

A. Yes. 11:01

Q. All right. I want to give you, I guess, an opportunity just to tell me just generally what are -- what are your criticisms of Teva with respect to their management and supervision of their supplier ZHP in this case? 11:01

MR. STANOCH: Objection to form. 11:01

But go ahead. 11:01

THE WITNESS: I have many criticisms. Is there something specific about their supplier and management that you would like me to respond to? 11:02

BY MS. LOCKARD: 11:02

Q. Well, we can walk through -- we can walk through the report if you prefer to do that. But are you able to give me sort of a broad version of what, you know, your -- your overarching criticism is with respect to Teva and their oversight of their suppliers? 11:02

MR. STANOCH: Objection to form. 11:02

THE WITNESS: In very general terms, my concern with Teva's approach to supplier management is they did not ask appropriate questions of the supplier. 11:02

Page 80

Supplier management is a highly critical area within GMP, mainly because the manufacturer has limited control over the material coming in because it's manufactured by someone else. 11:02

So the rigor in oversight is critical to -- to GMP compliance and to the safety, identity, strength, purity, quality of drug products that are going to be manufactured using that drug substance. 11:03

So the main criticism is that, although Teva may have employed some industry vehicles for monitoring, they didn't appear to use that information to really risk profile ZHP and to understand and question ZHP when issues or changes occurred in their process. 11:03

BY MS. LOCKARD: 11:03

Q. In Paragraph 24 -- or, excuse me. In paragraph -- hold on one second. Sorry. I just lost my notes. 11:03

All right. In Paragraph 37, when you are talking about "the purpose of the Current Good Manufacturing Practices" -- 11:04

A. Yes. 11:04

Q. -- you cite to a document that is the "Facts About Current Good Manufacturing Practices (CGMPs)"; correct? 11:04

Page 81

A. Yes. 11:04

MS. LOCKARD: All right. Let's mark this document as an exhibit, please. This is will be Exhibit 8 -- 11:04

MR. HARKINS: 9. 11:04

MS. LOCKARD: -- 9? 11:04

(Deposition Exhibit 9 was marked for identification and is attached hereto.) 11:04

BY MS. LOCKARD: 11:05

Q. And you quote from this document in your report, but there was some additional information in this I wanted to ask you about as well. 11:05

If you'll turn with me to Page 2 of this exhibit. 11:05

A. Under what heading? 11:05

Q. The last heading. 11:05

A. [As read]: 11:05

"If manufacturer is not following GMP [verbatim]..."? 11:05

Q. Correct. 11:05

And according to the FDA, it says that -- if you look at page -- sentence two [as read]: 11:05

"This kind of adulteration means that the drug was not manufactured under conditions that comply with CGMP. 11:05 11:06

Page 82

It does not mean that there is necessarily something wrong with the drug." Did I read that correctly? 11:06
A. Yes. 11:06
Q. And do you agree with that? 11:06
MR. STANOCH: Objection. Go ahead. 11:06
THE WITNESS: I recognize what FDA's purpose is in providing this document to the public. So they are -- I agree to the extent that they are trying to explain to a layman what this means. 11:06
BY MS. LOCKARD: 11:06
Q. So would you agree that, even if a drug is deemed adulterated by the FDA, it does not mean that there is necessarily something wrong with the drug, as FDA says? 11:06
MR. STANOCH: Objection to form. 11:06
THE WITNESS: I -- first, FDA does not designate something as being adulterated. Adulteration is a continuum of risk. There isn't a body that says something is adulterated or not within the industry. 11:06
And what this is saying basically for the layman, if I translate it into industry-ese, it would be that just because a product may meet its 11:07

Page 83

specifications does not mean that there is some -- that it wasn't manufactured in a way that would call that product adulterated. 11:07
So when they are saying here for the layman that it doesn't mean that there is necessarily something wrong with the drug, there wouldn't be an indicator from testing or from specification that the drug fails or that its therapeutic value is compromised. 11:07
So they are trying to explain very complex concepts from the industry for the layman. That is the purpose of this document. 11:07
This is written not to industry but to the general public. 11:07
BY MS. LOCKARD: 11:07
Q. Right. But you cited this in your report; correct? 11:07
A. I do cite it in my report but not in this section. 11:08
Q. Right. But you find certain items in this to be significant for your opinions, such that you cited it in your report. So I'm -- for purposes of completeness, I'm asking you about the other portions in this. 11:08
Do you understand? 11:08

Page 84

A. I do understand. 11:08
And I cite it in the report primarily to translate complex items to a layman reader. I recognize the reader of these reports are not a industry professional that has all the background and knowledge. 11:08
So this language helps to translate complex ideas about GMP to a layman. That's the reason I add or use this web article. And that's the purpose of this web article is to communicate very complex concepts of GMP to the layman. 11:08
Q. So this provides almost a common sense approach to the layman about what adulteration means. 11:09
Would you agree with that? 11:09
MR. STANOCH: Objection. 11:09
THE WITNESS: "Common sense" is probably not the right word. 11:09
Again, my viewpoint of this article is to translate concept -- or complex terms into something that the general public in America would be able to understand. 11:09
BY MS. LOCKARD: 11:09
Q. So you would agree, though, that a product that may be considered adulterated is not 11:09

Page 85

necessarily dangerous? 11:09
A. I can't speak to the danger of a product. That is a clinical effect. I can definitely speak to whether a product is adulterated based on GMP. 11:09
Q. Okay. What is your -- your working definition of what adulterated would mean? 11:09
A. So I use an industry standard to identify something that would be considered adulteration. The standard is called ICH Q9. It's the risk management ICH guidance. 11:09
Within this guidance, there is a description of a qualitative/quantitative way to evaluate risks. Risks for product adulteration would be a risk that we would use. It uses three categories: severity, occurrence, and detection. 11:10
And using those, I can identify something that would be a high potential for product adulteration. Something that may not be as high a potential for product adulteration. 11:10
So an example would be a person in manufacturing is not wearing a hair net. Wearing a hair net to cover their hair, prevent hair from getting into the product is a GMP requirement. 11:10
So how severe is a problem of getting hair 11:10

Page 86

in a product? Well, it is objectionable. It's probably not going to kill someone, if you will. But it is -- it is objectionable. 11:10

How often does it occur? Well, if one time somebody wasn't wearing a hair net, that is a very low occurrence. 11:10 11:11 11:11

And it's easily detected. I can see someone not wearing a hair net. 11:11 11:11

If I were to take that and say, "Hey, they never wear a hair net. This facility, no one wears a hair net," well, it's objectionable. It has a high-level of opportunity or of occurrence, but it still has a high-level detection. This starts to rise to the level of product adulteration. 11:11 11:11 11:11 11:11 11:11 11:11 11:11 11:11

There are other GMP requirements, unlike something like a hair net. For instance, a product coming from a supplier, a drug substance. I have -- it's very severe if there is an impurity like nitrosamine that could be a health or safety issue. So it's a high severity. 11:11 11:11 11:11 11:11 11:11 11:11 11:11 11:11

Again, I'm not an expert in clinical severities, but one can generally look at that as being a very high severity. 11:11 11:11 11:11

How often would something like that occur? Well, I use the drug substance every time I make the 11:12 11:12

Page 87

product. So the occurrence is extremely high. 11:12

Then there is the detection. Although it is not impossible to detect certain impurities or certain contaminants that may be in a drug substance using either GMP oversight or testing, but the detection level may be problematic. 11:12 11:12 11:12 11:12 11:12 11:12

Just like this article states or what I have quoted is that the general person taking a drug product won't be able to say, "Oh, the drug substance that was used here may have some problems." 11:12 11:12 11:12 11:12

So concerns in that GMP area rise to the level of great probability of product adulteration if there isn't great GMP control. 11:12 11:12 11:12

And that is my concern in my report. And my criticism of Torrent and Teva in that they didn't take the appropriate rigor with this potential for -- high potential for -- GMP potential for product adulteration. 11:12 11:12 11:12 11:13 11:13

So I use the standard to evaluate what -- what adulteration means, and it's discretionary, and one has to use good scientific judgment there. 11:13 11:13 11:13

Q. So is it your opinion that adulteration does not have a specific statutory definition in the FD&C Act? 11:13 11:13 11:13

Page 88

MR. STANOCH: Objection to form. 11:13

THE WITNESS: Certainly there is discussion of adulteration. I think that FDA has not been explicit that here is a line in GMP where adulteration occurs. 11:13 11:13 11:13 11:13

And, again, I'll restate, as I have stated previously, that FDA does not determine adulteration. They may use the word. But they do not have a specific level or definition of what adulteration is. 11:13 11:13 11:13 11:13 11:13

This is left to, again, the risk management that manufacturers use and that FDA promulgates. They say ICH Q9 is their viewpoint on how to do risk management for all aspects, including product adulteration as it relates to GMP. 11:13 11:13 11:14 11:14 11:14

BY MS. LOCKARD: 11:14

Q. Well -- and even under the ICH Q9 and the FDA rules and regulations, one violation of a cGMP alone does not render a product adulterated. 11:14 11:14 11:14

You would agree with that; correct? 11:14

MR. STANOCH: Objection to form. 11:14

THE WITNESS: I would not agree with that. I would agree that one needs to use the process that I have just described. 11:14 11:14 11:14

A single instance, if it meets the criteria of severity and occurrence and the lack of detection, 11:14 11:14

Page 89

that single instance can be considered a high potential for product adulteration. 11:14 11:14

It -- when I say "it depends," it depends on those categories and a risk assessment for those categories. It's not a number of violations. It is about a discretion -- a scientific judgment of the relative risk of -- of product adulteration based on the non-compliance. 11:14 11:14 11:14 11:14 11:15 11:15

BY MS. LOCKARD: 11:15

Q. Right. 11:15

So it's your opinion that whether or not a product has a high potential for adulteration is based on circumstances presented; right? 11:15 11:15 11:15 11:15

MR. STANOCH: Objection. 11:15

Go ahead. 11:15

THE WITNESS: It's -- it's -- it's based on the severity occurrence and detection levels of that particular GMP compliance concern. 11:15 11:15 11:15 11:15

BY MS. LOCKARD: 11:15

Q. So whether or not a product has a high potential for adulteration is based on those circumstances that you have just described: severity and... 11:15 11:15 11:15 11:15

A. I'm talking -- I'm not talking about whether a product is adulterated. I am talking 11:15 11:15

Page 90

about whether a GMP compliance concern will lead -- 11:15
or has the high potential to lead to product 11:16
adulteration. 11:16
So, again, my example of -- in this 11:16
matter -- again, I have all these high 11:16
probabilities. 11:16
A single occurrence of not -- of not 11:16
having great rigor around this process or program 11:16
could develop -- could -- could make one state, 11:16
"This product is adulterated," as opposed to a much 11:16
lower level GMP compliance concern where I can run 11:16
it through that same process. 11:16
But, again, it's about the risk of a GMP 11:16
compliance concern, not about that the product is 11:16
adulteration -- you know, I am not saying the 11:16
product -- that this says the product doesn't lead 11:16
to product adulteration. 11:16
You know, it's not about the product. 11:16
It's about -- that there is a high potential that 11:16
this product is adulterated because of this lack of 11:16
assurance and this GMP concern. 11:16
Q. So in this case, you do not intend to 11:16
offer any opinions that any defendants' product was 11:17
adulterated; correct? 11:17
MR. STANOCH: Objection. 11:17

Page 91

Go ahead. 11:17
THE WITNESS: I don't offer an opinion in my 11:17
report about the specific adulteration of a product. 11:17
I say that the products -- because of the 11:17
GMP concerns of the -- the firms, especially around 11:17
supplier management, that this leaves the high 11:17
potential that the product was adulterated. 11:17
I would believe that the product is 11:17
adulterated in the absence or lack of these types of 11:17
rigorous GMP controls around supplier management. 11:17
Again, that's my opinion running through ICH Q9 11:17
evaluation. 11:17
So, again, there isn't a specific level that 11:17
says this product is adulterated because of this. 11:17
If I read the law, I would say that every 11:17
product where any GMP concerns -- because that's the 11:17
way it is written -- is adulterated. That's not 11:17
reasonable. And that's not the way the industry 11:18
practices the evaluation of GMP concerns. 11:18
What I have just described to you is how the 11:18
industry practices GMP concern evaluation. 11:18
BY MS. LOCKARD: 11:18
Q. And so you would acknowledge there are 11:18
many instances where GMP issues are identified which 11:18
would not cause a product to be adulterated? 11:18

Page 92

MR. STANOCH: Objection to form. 11:18
THE WITNESS: I -- I agree that there are 11:18
low-level GMP concerns that would -- when run through 11:18
a risk evaluation, would have less probability of 11:18
causing a product to be adulterated. 11:18
BY MS. LOCKARD: 11:18
Q. Do you believe product manufacturers 11:18
determine for themselves whether the product is 11:18
adulterated? 11:18
A. I believe they should. Do they in 11:18
practice? In my experience, not often. Not often 11:18
enough. 11:18
So it is their responsibility to determine 11:18
if they are in compliance with GMPs and the impact 11:18
of their non-compliance on their products. 11:18
FDA is a regulator. They are not 11:19
responsible for the quality of products at firms. 11:19
The firm is responsible for that. 11:19
Q. But you don't plan to offer an opinion and 11:19
you have not offered an opinion in this case that 11:19
Teva's product was adulterated; correct? 11:19
MR. STANOCH: Objection. Asked and 11:19
answered. 11:19
THE WITNESS: I haven't stated that their 11:19
product is adulterated. I believe that their GMP 11:19

Page 93

practices have a high probability of creating products 11:19
that are adulterated. 11:19
BY MS. LOCKARD: 11:19
Q. Well, in your opinion, was Teva's product 11:19
adulterated or not? 11:19
MR. STANOCH: Objection to form. Asked and 11:19
answered. 11:19
MS. LOCKARD: He hasn't answered my 11:19
question. 11:19
MR. STANOCH: Disagree. 11:19
Go ahead and try. 11:19
THE WITNESS: I -- I have -- I only can 11:19
state that the concerns I have with their supplier 11:19
management would, in my opinion and in my risk 11:19
evaluation against ICH Q9, rise to the level of 11:19
product adulteration. 11:20
If I were the quality leader making that 11:20
discretionary decision, I would call that product 11:20
adulteration. 11:20
BY MS. LOCKARD: 11:20
Q. For what product would you call that 11:20
adulteration? 11:20
A. Again, these GMP practices and behaviors 11:20
were in effect for any supplier management program. 11:20
I haven't looked at other products or 11:20

Page 94

documents related to other products. So at this 11:20
point, I can only say this is for Valsartan. 11:20
But one would expect that they use similar 11:20
practices across all their supply base and that 11:20
other products may also -- there also may be 11:20
concerns in regard to product adulteration based on 11:20
their GMP practice. 11:21
Q. But would you say that every product that 11:21
was made in the facility would be adulterated just 11:21
by virtue of these concerns that you have addressed 11:21
with Valsartan? 11:21
MR. STANOCH: Objection to form. 11:21
THE WITNESS: I am not -- I can't make a 11:21
statement on whether each product is adulterated. 11:21
Again, the practice has a high probability 11:21
of leading to adulterated products. The determination 11:21
of a product being adulterated itself is -- is not 11:21
something I am opining on in my report. 11:21
BY MS. LOCKARD: 11:21
Q. Okay. So you are not -- you are not going 11:21
to give the opinion that any of the product 11:21
manufactured by Teva was adulterated? 11:21
A. No, I am not. I am only stating that the 11:21
practices they employed for supplier management were 11:21
sufficiently deficient that it would have a high 11:21

Page 95

probability of leading to product adulteration. 11:21
Q. And I understand that. But the words in 11:21
this case have meaning and are important. So I want 11:21
to make sure I understand how you are applying the 11:22
words such as "adulterated," which is an important 11:22
one in this instance. 11:22
Agreed? 11:22
A. Yes. Agreed. 11:22
Q. Now -- 11:22
A. I understand your concern. 11:22
Q. -- are you aware that FDA has never made 11:22
any statement that Teva's product was adulterated? 11:22
A. I am secondarily aware of that. But, 11:22
again, my viewpoint is that FDA doesn't make a 11:22
determination if something is adulterated. There 11:22
isn't a -- something in regulation that FDA could 11:22
use or that industry could use to say, "This is a 11:22
product adulteration." It is a discretionary 11:22
risk-based evaluation. 11:22
Now, FDA may make statements based on 11:22
their risk evaluation using the same concepts that 11:22
I'm describing for my ICH Q9 that a product is 11:22
adulterated. For instance, they make that statement 11:22
about ZHP's product. 11:22
But, again, the concept of adulteration, 11:23

Page 96

as it relates to GMP, is based on risk. And in my 11:23
opinion, if I were to run this scenario, what 11:23
happened with Teva's oversight and what happened 11:23
with this product from ZHP, a drug substance, that 11:23
this would rise to a level of adulteration. 11:23
Q. But as you said, the comments that FDA 11:23
made about ZHP's product being adulterated, they 11:23
could have made comments about Teva's product 11:23
similarly but they did not; right? 11:23
A. They chose not, and I can't comment as to 11:23
why that would be the case. 11:23
Again, if I as an industry professional or 11:23
as if I were standing as the leader at Teva in 11:23
evaluation of this, I would describe this as product 11:23
adulteration. 11:23
Q. Do you agree that, for consumers currently 11:23
taking medicines from a company that was not 11:23
following cGMPs, FDA usually advises consumers not 11:24
to interrupt their drug therapy? 11:24
MR. STANOCH: Objection to form. 11:24
THE WITNESS: Yes. I have read that in 11:24
disclosures from FDA. 11:24
The risk of a compliance concern against the 11:24
risk of a diseased state by not taking a medication, 11:24
that risk profile may be sufficient where it's 11:24

Page 97

appropriate to continue therapy because there is a 11:24
higher risk of a -- of a clinical outcome that is -- 11:24
that is deleterious. 11:24
That does not mean that that product should 11:24
be on the market or that that product is not 11:24
adulterated. 11:24
BY MS. LOCKARD: 11:24
Q. But adulterated is not the same thing as a 11:24
product being unsafe. 11:24
You would agree with that; correct? 11:24
MR. STANOCH: Objection to form. 11:24
Go ahead. 11:24
THE WITNESS: A product that is unsafe is 11:24
adulterated, in my opinion. 11:24
BY MS. LOCKARD: 11:24
Q. Well, my question was you would agree that 11:24
a product that is adulterated is not necessarily 11:25
unsafe. 11:25
MR. STANOCH: Objection to form. 11:25
THE WITNESS: I think that a product that 11:25
has GMP concerns that would lead a product to be 11:25
adulterated -- there's a lack of assurance that that 11:25
product is safe. 11:25
BY MS. LOCKARD: 11:25
Q. You're not offering opinions about whether 11:25

Page 98

the drugs in this case were dangerous or not; right? 11:25
A. No. 11:25
Q. And you're not offering opinions in this 11:25
case about whether there was a safety concern with 11:25
the drugs that were produced? 11:25
A. No. 11:25
Q. And you're not offering opinions about 11:25
whether the drugs at issue in this case were, quote, 11:25
"unsafe"; right? 11:25
A. No. 11:25
Q. And one of the reasons that FDA advises 11:25
consumers taking medications from a company that may 11:25
be found not to be following the cGMPs is because 11:25
withholding the drug could have serious implications 11:25
for their health. FDA has stated that. 11:25
You have seen that in FDA statements; 11:26
correct? 11:26
MR. STANOCH: Objection. 11:26
THE WITNESS: Yes. 11:26
BY MS. LOCKARD: 11:26
Q. And, in fact, it's so stated in Exhibit 11:26
Number 9 that we were going through? 11:26
A. It is. 11:26
Q. And if you follow back with me on the 11:26
Exhibit Number 9 in the last paragraph, midway 11:26

Page 99

through, the FDA states [as read]: 11:26
"Regulatory actions against 11:26
companies with poor cGMPs are often 11:26
intended to prevent the possibility of 11:26
unsafe and/or ineffective drugs." 11:26
Do you agree with that? 11:26
A. I -- I do agree with that. And that is 11:26
exactly what I have just stated previously. 11:26
Q. And it is consistent with your opinion in 11:26
this case? 11:26
A. It is. 11:26
Q. FDA goes on to state [as read]: 11:26
"In rare cases, FDA regulatory 11:26
action is intended to stop the 11:26
distribution of manufacturing of 11:26
violative product." 11:26
Do you see that? 11:26
A. If you could just give me the heading of 11:27
where you are at. And I apologize. 11:27
Q. It's the last paragraph. 11:27
A. If manufactured -- if the manufacturer is 11:27
not following. 11:27
Here. Okay. 11:27
Q. It's the last paragraph. 11:27
A. Right. 11:27

Page 100

Q. Very end of the... 11:27
A. [As read]: 11:27
"FDA regulatory action is intended 11:27
to stop distribution...." 11:27
Q. Yeah. 11:27
[As read]: 11:27
"In rare cases, FDA regulatory 11:27
action is intended to stop the 11:27
distribution or manufacturing of 11:27
violative product." 11:27
A. Yes. 11:27
Q. [As read]: 11:27
"The impact of cGMP violations 11:27
depends on the nature of those 11:27
violations and on the specific drugs 11:27
involved." 11:27
You agree with that? 11:27
A. I do. 11:27
Q. [As read]: 11:27
"A drug manufactured in violation of 11:27
cGMP may still meet its labeled 11:27
specifications, and the risk that the 11:27
drug is unsafe or ineffective could be 11:27
minimal." 11:27
You agree with that as well; right? 11:27

Page 101

A. I do. Yes. 11:27
This is, again, in -- consistent with the 11:27
way I have just described this, that although a 11:28
product meets its specification does not mean that 11:28
it's not adulterated or that it's safe. 11:28
It also states that -- that it's a -- the 11:28
idea of adulteration depends on the specific type of 11:28
GMP violation, and that that's something that should 11:28
be evaluated from a risk perspective. And, again, 11:28
as I described, I use ICH Q9 to do so. 11:28
Q. And the document goes on to say [as read]: 11:28
"Thus, FDA's advice will be specific 11:28
to the circumstances." 11:28
Do you see that? 11:28
A. I do. 11:28
Q. So if FDA feels that the circumstances of 11:28
the violations are frequent or severe, they can take 11:28
action to ask that the drug be removed from the 11:28
market; correct? 11:28
A. They could. 11:29
Q. And -- and in that case, FDA says 11:29
[as read]: 11:29
"Health care professionals are best 11:29
able to balance the risks and benefits 11:29
and make the right decisions for their 11:29

Page 102

patients." 11:29
MR. STANOCH: Objection to form. 11:29
THE WITNESS: That's what the document says. 11:29
Yes. 11:29
BY MS. LOCKARD: 11:29
Q. You agree that observations made during a 11:29
regulatory inspection generally relate to cGMPs? 11:29
MR. STANOCH: Objection to form. 11:29
THE WITNESS: Generally. I agree with that, 11:29
yes. Generally. 11:29
BY MS. LOCKARD: 11:29
Q. And would you agree those observations in 11:29
a 483 or an EIR do not necessarily indicate the 11:29
product is being manufactured in violation of cGMPs? 11:29
MR. STANOCH: Objection to form. 11:29
THE WITNESS: No, I don't agree with that. 11:29
If -- if FDA has identified an observation, it -- the 11:29
product is being manufactured in some deficient way 11:30
based on GMP. It's the reason that they are providing 11:30
an observation. 11:30
BY MS. LOCKARD: 11:30
Q. So every observation found in a 483 is a 11:30
violation of a cGMP, in your opinion? 11:30
MR. STANOCH: Objection to form. 11:30
THE WITNESS: Yes. And FDA will routinely 11:30

Page 103

provide the reference to the GMP where their company 11:30
is violative. 11:30
So, yeah, they're -- the reason they 11:30
identify a problem is because of a compliance issue 11:30
with GMP. 11:30
BY MS. LOCKARD: 11:30
Q. Don't they frequently identify issues in a 11:30
483 that do not rise to the level of a violation of 11:30
a cGMP? 11:30
A. No. 11:30
Q. You disagree with that? 11:30
A. I disagree with that. It may not -- 11:30
again, the relative risk of each observation as it 11:30
relates to product or product safety or 11:30
adulteration. That is a whole different evaluation. 11:30
Every observation that is provided by FDA 11:30
to a firm, unless otherwise noted as a 11:31
recommendation or an enhancement -- a potential 11:31
enhancement, which FDA does not normally provide 11:31
firms, is a violation of cGMP. 11:31
There may be a discussion or disagreement 11:31
between the firm and FDA as to the -- whether it's 11:31
truly violative or not. But if -- if it ends up in 11:31
a 483, it's a violation of cGMP. 11:31
Q. And in this case, to your knowledge, Teva 11:31

Page 104

never received a 483 observation regarding any cGMP 11:31
violation with respect to their handling of the 11:31
impurity or the recall; correct? 11:31
MR. STANOCH: Objection to form. 11:31
THE WITNESS: I am -- I can't speak to that 11:31
without looking at all of the regulatory history 11:31
associated with -- with Teva -- Teva's relationship 11:31
with FDA. 11:31
But because FDA did not find something or 11:31
give an observation does not mean that there aren't 11:31
non-compliances. 11:31
This is a -- an iceberg approach. It's a 11:31
point in time. FDA has a very small amount of time to 11:32
evaluate a quality system. It's a highly managed 11:32
activity, the firm, and as far as managing FDA's work 11:32
at their facility for an inspection, highly managed. 11:32
So when observations occur from a 483, that 11:32
is the tip of the iceberg. 11:32
I, in my experience, know that there are 11:32
significant other vulnerabilities that were not 11:32
identified by FDA. 11:32
So firm's error when they state, "FDA never 11:32
cited this." I hear this routinely from clients: 11:32
"FDA has never cited me for this. But, Phil, you say 11:32
it's non-compliant." 11:32

Page 105

FDA has -- just because FDA didn't cite it 11:32
doesn't mean it's not non-compliant. 11:32
BY MS. LOCKARD: 11:32
Q. In this situation, where FDA, you would 11:32
agree, spent significant time and resources on the 11:32
issue of nitrosamine impurities in drugs -- 11:32
MR. STANOCH: Objection. 11:32
BY MS. LOCKARD: 11:32
Q. -- correct? 11:32
MR. STANOCH: Objection. 11:32
THE WITNESS: To -- to the -- what -- what 11:32
is an amount of time? What does that mean? An 11:33
excessive amount of time or that they spent a 11:33
sufficient amount of time or that they spent, you 11:33
know, an amount of time that would cause them to fully 11:33
evaluate a specific area? 11:33
None of that I can agree with as being true. 11:33
FDA is a regulatory body and have limited 11:33
resources. Regardless of the issue that may affect 11:33
the public health, they have limited amounts of 11:33
resources that they can apply to that. 11:33
It's the firm's responsibility to apply 11:33
those resources internally to their own systems to 11:33
evaluate non-compliance and to bring that to the 11:33
forefront to correct and to prevent in the future. 11:33

Page 106

So it's not FDA's role to do any of that work. 11:33
BY MS. LOCKARD: 11:33
Q. So -- but you would agree FDA found the time and resources to issue 483s to other manufacturers who were involved in this litigation? 11:33 11:34
A. To the extent that they inspected them and found non-compliance, of course, they would. 11:34 11:34
Q. Did you ask counsel or look in -- on the FDA website to try to determine whether there had been any action taken against Teva with respect to their involvement in the impurity issue? 11:34 11:34 11:34 11:34
MR. STANOCH: Objection. 11:34
Go ahead. 11:34
THE WITNESS: What I opined on in my report had nothing to do with FDA's enforcement activity with Teva. 11:34 11:34
I'm not making a statement within the report that that was an appropriate level or that FDA did great enforcement with any of -- whether -- whether it's Teva or Torrent. I make no statements about FDA's enforcement activity with the firms. 11:34 11:34 11:34 11:34 11:34
My report is purely about deficiencies within their supplier management program, which they were responsible for as far as oversight of suppliers. 11:34 11:34 11:34

Page 107

It has nothing to do with FDA's observations. 11:35
BY MS. LOCKARD: 11:35
Q. So the FDA's observations about Teva and their handling of the impurity issue has nothing to do with your opinion. 11:35 11:35 11:35
Is that your testimony? 11:35
MR. STANOCH: Objection to form. 11:35
THE WITNESS: I'm not saying it has nothing. It's a -- it's an indicator or it's an input. 11:35 11:35 11:35
But what I am saying is that observations from FDA are not the sole input that determines whether something is non-compliant or whether actions taken by a firm were appropriate or even whether or not FDA chooses to enforce or do an enforcement activity. 11:35 11:35 11:35 11:35 11:35 11:35 11:35
It's, again, the firm's responsibility to remain compliant with GMP. FDA's role in this is purely as a regulator or a monitor. 11:35 11:35 11:35 11:35
So that -- that's my viewpoint. And that's what I have described in my report as well. 11:35 11:35 11:35
BY MS. LOCKARD: 11:35
Q. Wouldn't it be an important factor in your review and report to know whether or not FDA had taken any enforcement action against Teva? 11:35 11:36 11:36
MR. STANOCH: Objection. 11:36

Page 108

THE WITNESS: It's important certainly. I'm not saying that regulatory history or regulatory compliance history is not important. For me it is the least important input, especially for an international supplier or for a facility that is outside of the U.S. 11:36 11:36 11:36 11:36 11:36 11:36
in that an inspection from FDA is announced. They know FDA is coming, and they can defend themselves. 11:36 11:36 11:36
I know that this is -- the least reliable indicator of compliance is FDA's 483 or their observations at a firm. 11:36 11:36 11:36 11:36
BY MS. LOCKARD: 11:36
Q. Well, you state in your report on Page 30 [verbatim] -- and I am quoting [as read]: 11:36 11:36
"Scientists with varied and appropriate backgrounds and expertise at FDA review all elements of the submitted product application and determine if the as-described and represented product's benefits outweigh the known risks and side effects. 11:36 11:36 11:37 11:37 11:37 11:37 11:37 11:37
"If FDA determines that the benefits do outweigh the clinical risks and that a high quality product can be consistently manufactured by the manufacturer based on the information 11:37 11:37 11:37 11:37 11:37 11:37

Page 109

submitted, the product will gain approval, meaning it can be legally marketed and distributed to the US market." 11:37 11:37 11:37 11:37
You then state [as read]: 11:37
"The product will continue to be monitored by the FDA post-approval to ensure FDA compliance." 11:37 11:37 11:37
Correct? 11:37
A. Yes. That's what I state there. 11:37
Q. And you include this because this is an important component of the regulatory system in the United States, that FDA will continue to monitor post-approval to ensure compliance with their cGMPs; right? 11:37 11:37 11:37 11:37 11:37 11:37
A. It is. 11:37
MR. STANOCH: Objection. 11:37
THE WITNESS: It is a input. I am stating it is not the most important input. It is a input. 11:37 11:38 11:38
Certainly the regulator inspects. And the regulator provides information to a firm. 11:38 11:38 11:38
But in my experience -- and I have managed FDA inspections for many firms and have helped to support firms in response to FDA for observations -- it's the least important indicator. 11:38 11:38 11:38 11:38

Page 110

And the Paragraph Number 30 is about what is 11:38
called "application compliance." It's about the 11:38
compliance that the ANDA, which is different than GMP 11:38
compliance. Those are two separate avenues. 11:38
BY MS. LOCKARD: 11:38
Q. The -- I agree with you that the paragraph 11:38
begins discussing the submission of the ANDA. The 11:38
last sentence, though, that says [as read]: 11:38
"The product will continue to be 11:38
marketed [verbatim] by the FDA 11:38
post-approval to ensure FDA 11:38
compliance." 11:38
That relates not to the submission, that 11:38
relates to ongoing compliance? 11:38
A. No. It relates to the submission. 11:38
Post-market approval or post-market 11:39
monitoring is supplements, CB-30s, PAS [phonetic] -- 11:39
Q. Inspections? 11:39
A. -- amount of supplier -- 11:39
Not inspections. Inspections is the 11:39
Office of Compliance. This -- inspections are about 11:39
GMP -- cGMP compliance. This is about application 11:39
compliance. 11:39
So post-approval monitoring is done by FDA 11:39
of the application; i.e., submit an annual report 11:39

Page 111

every year, identifies the changes that I have made. 11:39
That's the monitoring I'm referring to here. Not 11:39
cGMP compliance. 11:39
Now, the application -- certainly FDA 11:39
has -- they have the application, and there are all 11:39
kinds of regulations on how I need to maintenance 11:39
the application during its lifecycle. That's what 11:39
I'm referring to as post-approval changes or 11:39
post-approval monitoring by FDA. 11:39
These are two different things, just so 11:40
I'm clear. 11:40
Q. I am -- 11:40
A. I'll -- 11:40
Q. I understand your testimony -- 11:40
A. Okay. 11:40
Q. -- on that point. 11:40
You are -- your statement, though, is that 11:40
the FDA's continuing monitoring of compliance with 11:40
cGMP is the least important fact in your review? 11:40
MR. STANOCH: Objection to form. 11:40
THE WITNESS: It's the least important input 11:40
to any firm's risk evaluation of their GMP compliance. 11:40
And to -- it's -- I have considered it, 11:40
certainly. I am concerned as it relates to 11:40
observations from FDA, but I'm more concerned in the 11:40

Page 112

direct records from Teva or Torrent that identify 11:40
their lack of compliance. Whether FDA observed this 11:40
condition or not does not relate to their level of 11:40
compliance. 11:40
So it's an input, I agree. I will 11:40
acknowledge that regulatory -- what we call regulatory 11:40
surveillance in the industry, understanding what 11:40
observations FDA has identified or other regulatory 11:41
bodies, it's an input. A singular input. 11:41
BY MS. LOCKARD: 11:41
Q. The least important? 11:41
MR. STANOCH: Let him finish his question 11:41
[verbatim], Counsel. 11:41
MS. LOCKARD: Okay. I will, but he is 11:41
not -- 11:41
MR. STANOCH: He answering. 11:41
MS. LOCKARD: -- answering. He's -- 11:41
MR. STANOCH: Let him finish his answer. 11:41
MS. LOCKARD: -- just giving a lecture. 11:41
MR. STANOCH: Now, you are cutting me off. 11:41
Let the witness finish his answer. Then you 11:41
can ask your question. You know how -- that's how it 11:41
works. 11:41
BY MS. LOCKARD: 11:41
Q. What was the question you are answering, 11:41

Page 113

by the way? 11:41
A. The question I'm answering, as I 11:41
understand it, is if I believe that FDA's 11:41
observations are the least important input. 11:41
I believe they are a input, but there are 11:41
equally important or more important inputs into risk 11:41
that evaluation. 11:41
So I'm not saying that it is not 11:41
important. Certainly if you receive a 483 from FDA, 11:41
you are going to respond to it. In actuality, it's 11:41
voluntary to respond in the industry to a 483. It's 11:41
voluntary. I don't even need to from a statutory 11:42
perspective. Most firms do, obviously. 11:42
So it's a -- it's a input. 11:42
And when I work with clients, a routine 11:42
response I get is "FDA never cited me for this, and 11:42
it doesn't matter. It's insignificant." 11:42
They at a point in time -- they came once 11:42
in the last two years for three days. It's -- "You 11:42
are here every day, sir. Your auditors are here 11:42
every day. I'm more concerned with what you have 11:42
found about your own vulnerabilities than what FDA 11:42
has found." 11:42
Q. The clients that you do work for, they 11:42
certainly would not find a 483 noting observations 11:42

Page 114

to be insignificant, would they? 11:42
A. From a regulatory perspective or from 11:42
their level of GMP compliance? 11:42
Q. From any perspective. 11:42
A. It's important because you -- you are 11:42
going to placate the regulator. 11:43
I'm saying in practice, in my experience, 11:43
the inputs to whether a system is compliant, 11:43
observations from FDA is of lower significance 11:43
because it's such a small finite inspection that 11:43
happens so infrequently, and it's not their role. 11:43
They have asked the industry to 11:43
self-regulate that is their mantra to us. "You are 11:43
responsible." 11:43
In most warning letters, it says, "Hey, we 11:43
have identified these three significant areas, but 11:43
you are responsible to ensure compliance with all 11:43
the rest of the GMP." 11:43
So whose input is most important? The 11:43
firm's input. 11:43
Q. And so the most important input from your 11:43
perspective is whether or not the firm determines 11:43
that it was compliant or not? 11:43
MR. STANOCH: Objection to form. 11:43
THE WITNESS: Whether or not the firm has 11:44

Page 115

appropriately, based on industry standard and guidance 11:44
and the regulation, applied the GMP, the cGMP through 11:44
their quality system. That's the most important 11:44
element. 11:44
BY MS. LOCKARD: 11:44
Q. And so the most important element in your 11:44
review is what the manufacturer themselves have -- 11:44
has determined about their own compliance? 11:44
MR. STANOCH: Objection to form. Misstates 11:44
testimony. 11:44
Go ahead. 11:44
THE WITNESS: It's what their compliance is 11:44
at the firm. Whether they identify it they -- again, 11:44
the industry is chartered to self-regulate. Many 11:44
firms don't do a great job of self-regulation. I help 11:44
firms with self-regulation. That's what I do for a 11:44
living. 11:44
So do I agree that the firms find everything 11:44
or every compliance issue that they have? No, they 11:44
don't. But at least they have more opportunity to do 11:44
so. They are there every day. FDA is only there once 11:44
every two years. 11:45
BY MS. LOCKARD: 11:45
Q. Well -- so if FDA's judgment as to whether 11:45
or not the individual firm is compliant is such an 11:45

Page 116

insignificant factor, then the judge of whether or 11:45
not the company is compliant or acting as a 11:45
reasonable manufacturer has to come from the 11:45
manufacturer itself. 11:45
That's what you are saying. 11:45
A. It does -- 11:45
MR. STANOCH: Objection to form. 11:45
Go ahead. 11:45
THE WITNESS: I'm sorry. 11:45
It does or, in my cases, the firm is no 11:45
longer trusted for that purpose. 11:45
And this is -- again, something I do for a 11:45
living -- where a third-party will be brought in to 11:45
make all of those decisions for them. 11:45
In many warning letter activities or in 11:45
consent decree activities, FDA enforces. And what the 11:45
firm will do in response is -- because FDA doesn't 11:45
trust them any longer to self-regulate, they bring in 11:45
a third party. 11:45
They'll bring in someone like myself to make 11:45
those decisions for them. Because they are no longer 11:46
reputable or reliable to make good cGMP decisions. 11:46
So, yes, they are responsible for it. And 11:46
in the routine, one can only expect that they make 11:46
great GMP decisions. 11:46

Page 117

In enforcement activities and when FDA finds 11:46
long-standing problems or problems that are -- with 11:46
compliance that, you know, each time they come for an 11:46
inspection they find recidivism, same types of 11:46
problems not corrected, they are going to stop 11:46
trusting that organization. And the quality unit 11:46
within that organization will be set aside and a third 11:46
party will come in to do that evaluation. 11:46
BY MS. LOCKARD: 11:46
Q. Did FDA in this case ever determine that 11:46
Teva was a recidivist or no longer trusted? 11:46
A. Not that I am aware of. 11:46
Q. Did FDA ever make any pronouncement that 11:46
Teva was no longer reputable or reliable as a drug 11:46
manufacturer? 11:47
A. Not that I am aware of. 11:47
Q. Did FDA or any other body order that a 11:47
third party be brought in to make decisions for Teva 11:47
and it's quality team? 11:47
A. Not that I am aware of. But I'm sure that 11:47
Teva did bring in consultants and third parties to 11:47
assist them with this issue. 11:47
Q. How do you know that? 11:47
A. It would be an industry standard practice 11:47
to bring in third parties normally to help with 11:47

Page 118

issues like this particular issue. 11:47
I don't know that that occurred. But it 11:47
wouldn't surprise me, I guess, if that occurred. 11:47
Q. So now you are speculating about whether 11:47
Teva brought in a third party to consult? 11:47
A. I -- 11:47
MR. STANOCH: Objection to form. Misstates 11:47
the testimony. 11:47
THE WITNESS: I withdraw that. I can't -- 11:47
MR. STANOCH: Go ahead. 11:47
BY MS. LOCKARD: 11:47
Q. So based on your hierarchy and the 11:47
observations in the FDA 483 related to a supplier -- 11:47
strike that. 11:47
Based on the hierarchy you have described, 11:48
observations in a -- in an FDA 483 related a 11:48
supplier would be the least important input to a 11:48
finished dose manufacturer in evaluating that 11:48
supplier? 11:48
A. That's not what I said. 11:48
MR. STANOCH: Objection to form. 11:48
THE WITNESS: What I said was at the firm 11:48
itself it's the least -- one of the least important 11:48
inputs. It gets -- because they are there every day. 11:48
When it relates to a supplier, I am not 11:48

Page 119

there any day. Maybe once or twice. Maybe every two 11:48
years or three years I may visit them to do 11:48
verification. 11:48
So, yeah, FDA's input is a major input for a 11:48
supplier because I don't have control over the 11:48
facility. I have control over my own facility. 11:48
Okay. So you are asking me what inputs are 11:48
important for a supplier. Well, certainly FDA's 11:48
enforcement activity or observations from a 483 have 11:49
much more significant importance when it relates to a 11:49
supplier in me evaluating the relative risk of that 11:49
supplier and use of their drug substance. 11:49
BY MS. LOCKARD: 11:49
Q. So as a finished dose manufacturer, it's 11:49
reasonable to rely on the FDA and their activities 11:49
with respect to issuing 483s and inspections for a 11:49
supplier? 11:49
MR. STANOCH: Objection to -- 11:49
BY MS. LOCKARD: 11:49
Q. Because -- because the manufacturing 11:49
finished dose manufacturer is not there every day? 11:49
MR. STANOCH: Objection to form. 11:49
THE WITNESS: I agree it's an important 11:49
input. But it's not the only input. 11:49
///

Page 120

BY MS. LOCKARD: 11:49
Q. The FDA's -- 11:49
A. The FDA's observations are an important 11:49
input for the finish drug manufacturer to evaluate 11:49
as it relates to whether that supplier is high risk 11:49
or whether the material is coming from that 11:49
supplier -- that I should scrutinize them more 11:49
heavily. 11:50
There are other systems that are required 11:50
by the cGMP that are outside of just the input of 11:50
what FDA said about the supplier. 11:50
Because, again, the same problems exist as 11:50
far as oversight by FDA or the supplier, especially 11:50
an overseas supplier. The inspection that is 11:50
performed there is done infrequently. It's planned. 11:50
So the manufacturer, the supplier has time to plan 11:50
and manage FDA's inspection. 11:50
So I am going to -- because I have less 11:50
control over a supplier, I'm going to probably give 11:50
more credence and risk evaluation because it's one 11:50
of the few inputs I have about a supplier. 11:50
So it's -- but it's not the only input. I 11:50
can't make a general evaluation of a supplier purely 11:50
based on enforcement activity or on whether or not 11:50
an observation was cited by FDA during an 11:50

Page 121

inspection. 11:50
Q. So then you would agree that FDA 11:50
inspections and observations are an important input 11:50
to a finished dose manufacturer when evaluating a 11:51
supplier because it's one of the few inputs the 11:51
supplier has? 11:51
MR. STANOCH: Objection to form. 11:51
THE WITNESS: I -- I agree with that. Yes. 11:51
MS. LOCKARD: So let me introduce another 11:51
exhibit here. 11:51
And we're up to what? 11:51
THE REPORTER: 10. 11:51
MR. HARKINS: 10. 11:51
MS. LOCKARD: 10. 11:51
(Deposition Exhibit 10 was marked for 11:51
identification and is attached hereto.) 11:51
BY MS. LOCKARD: 11:51
Q. This is another document that was cited in 11:51
your report, Mr. Russ. 11:51
Do you recognize this document? 11:51
A. I do. 11:51
Q. What is this document? 11:51
A. Again, this is a question-and-answers 11:51
document helping to describe and helping to answer 11:51
general questions for industry and the public as it 11:51

Page 122

relates to the GMP. 11:51
Q. And you cited from this document as well 11:51
in your report on Page 8 -- correct? -- in 11:51
Paragraph 46? 11:51
A. I do cite from this document. Let me just 11:52
check that. 11:52
[Witness reviews document]. 11:52
Yes. 11:52
Q. Do you need more time to review? 11:54
A. No. I am sorry. 11:54
I am familiar with this document. 11:54
Q. Okay. And you agree that FDA guidance 11:54
documents represent FDA's current thinking on a 11:54
topic. It's -- they are not binding on 11:54
manufacturers; correct? 11:54
A. Agreed. This is not a guidance document. 11:54
This is just a Q&A. Again, this is published just 11:54
as general questions. This is not a guidance 11:54
document. 11:54
Q. In the hierarchy of rules, regulations, 11:54
guidance documents, and so forth, this would be even 11:54
less binding or -- or... 11:54
A. I am just stating it's not a guidance 11:55
document. 11:55
Q. Okay. 11:55

Page 123

A. All -- all information, whether it's 11:55
industry standard information, literature, guidance, 11:55
there's no hierarchy of what is important. 11:55
This document along with guidances publish 11:55
what FDA's viewpoint is. 11:55
When guidances or other documents say that 11:55
this is a mandatory compliance item, it means it's 11:55
not in the regulation. 11:55
But, you know, there's certainly been -- 11:55
the industry knows from -- actually, previous 11:55
litigation that guidance, the "C" in "cGMP," the 11:55
"Current" in "Good Manufacturing Practice," 11:55
constitutes industry standards, things that FDA 11:55
says, presentations, those different items. 11:55
There is no hierarchy that something is 11:55
less important as it relates to published 11:56
information about GMP manufacturing. 11:56
Q. Well, wouldn't you agree that guidance 11:56
documents are less important than the cGMP 11:56
regulations? 11:56
A. No. No, not in any way. That they are 11:56
less important? 11:56
Q. Would you agree the guidance documents are 11:56
not binding on manufacturers? 11:56
MR. STANOCH: Objection. Asked and 11:56

Page 124

answered. 11:56
THE WITNESS: I agree that a guidance 11:56
document states disclaimer that it's not a binding 11:56
regulation. That is in 21 CFR 210 or 211. 11:56
But in practice FDA enforces on guidance 11:56
documents and industry accepts guidance documents as 11:56
regulatory standard. 11:56
If -- if anything from a guidance document 11:56
appears in a firm's standard operating procedure, it 11:56
becomes enforceable. 11:56
So if I adopt anything from a guidance, it 11:56
is now enforceable. 11:57
BY MS. LOCKARD: 11:57
Q. But you are taking it a step farther, 11:57
though. 11:57
A. Okay. 11:57
Q. We're not -- we're not -- we haven't seen 11:57
any operating procedures or policies that adopt a 11:57
guidance right now. 11:57
A. Uh-huh. 11:57
Q. We are talking generally about a guidance 11:57
issued by the FDA. 11:57
It -- it does not establish the law that a 11:57
company must follow. 11:57
You would agree with that? 11:57

Page 125

A. 21 CFR 210/211, Food and Drug Cosmetic 11:57
Act. Yes, those are the laws. 11:57
Q. The laws are the cGMPs? 11:57
A. The laws are the cGMPs. Agreed. 11:57
Q. The guidance documents do not make the 11:57
law. 11:57
You agree with that? 11:57
A. I agree that they are identified as 11:57
non-binding. 11:57
But I clarify that in the way that the 11:57
industry uses these documents and the way FDA uses 11:57
these documents that they are equally as enforceable 11:57
as the regulatory standard, you know, 210 and 211. 11:57
Q. Doesn't the FDA actually state that they 11:57
allow for alternative of approaches if the company 11:57
follows the statute and regs -- alternative 11:58
approaches to the guidance document if the company 11:58
follows the statute and the regulations? 11:58
MR. STANOCH: Objection to form. 11:58
THE WITNESS: Yes. That is true as well 11:58
that there -- again, this is the idea of 11:58
self-regulation. FDA is not going to instruct you on 11:58
everything that you need to do. 11:58
You can apply appropriate measures from the 11:58
cGMP for your quality system. 11:58

Page 126

The way industry in general practices is everyone tries to do the same thing, and normally that is what is from the guidance document. 11:58
It's difficult to look different. Although, it's allowed, it's very, very, very rarely employed. 11:58
BY MS. LOCKARD: 11:58
Q. Hasn't the FDA stated the use of the word, quote, "should" in their guidances means that something is suggested or recommended and not required? 11:58 11:59 11:59
MR. STANOCH: Objection. 11:59
THE WITNESS: Agreed. And, again, in practice when FDA says "should," most firms will, shall. 11:59 11:59 11:59
BY MS. LOCKARD: 11:59
Q. Now, this exhibit that we are looking at here you said is a Q&A for the general public; right? 11:59 11:59 11:59
A. This is a Q&A for the public but also mostly used by industry. These are specific questions about the regulation itself. 11:59 11:59 11:59
The previous article that we looked at is more "This is kind of what the GMP is." 11:59 11:59
These are specific responses to questions that FDA has received from industry. The public 11:59 11:59

Page 127

probably is not asking these types of questions. 11:59
Q. Okay. So you -- your position is the audience for this document, the Q&A, is somewhat different from the intended audience for the prior document that you said was meant for the general public? 11:59 11:59 12:00 12:00 12:00
A. It is -- it is. This document is Q&A. It's available, obviously, publicly to anyone who looks it up on the website, but the use of this type of a document would be industry more than likely. 12:00 12:00 12:00 12:00
Q. Is this the basis for your opinion that the finished dose manufacturer needs to do its own independent testing? 12:00 12:00 12:00
MR. STANOCH: Objection to form. 12:00
THE WITNESS: I have not made a statement or have expectation that the finished dose manufacturer needs to do their own testing for drug substances. 12:00 12:00 12:00
The regulation allows for receipt of drug substances using the supplier's certificate of analysis. So I have not used this document or any other documents to state that all firms must do full testing, if you will, of drug substances. 12:00 12:01 12:01 12:01 12:01
BY MS. LOCKARD: 12:01
Q. Okay. So your opinion is that it's reasonable and appropriate for a finished dose 12:01 12:01

Page 128

manufacturer not to do full testing of all API? 12:01
MR. STANOCH: Objection to form. 12:01
THE WITNESS: It is, but they must provide evaluation to show that the supplier's data is reliable. 12:01 12:01 12:01
So it's trust but verify. So the regulation allows me to receive materials on a certificate of analysis, but I must do some independent evaluation -- whether that be through testing or audits, data review -- that would give me assurance about the reliability of that supplier and of -- and of the data that they are -- that underlies and supports the values they have provided me on a certificate of analysis. 12:01 12:01 12:01 12:01 12:02 12:02 12:02 12:02
BY MS. LOCKARD: 12:02
Q. So you would agree that a finished dose manufacturer is not required to test every batch of API itself, provided that the manufacturer establishes the reliability of the supplier's analysis through appropriate validation of their test results? 12:02 12:02 12:02 12:02 12:02 12:02
MR. STANOCH: Objection to form. 12:02
THE WITNESS: It's not only appropriate evaluation of their test results, but they -- there is other elements of evaluation for a product -- or for 12:02 12:02 12:02

Page 129

reliability. 12:02
BY MS. LOCKARD: 12:02
Q. What are the other elements? 12:02
A. Whether or not the supplier is in compliance with the cGMP or ICH Q7, which would be for APIs or -- which is active pharmaceutical ingredients or drug substances. 12:02 12:02 12:02 12:02
It could also be evaluation through changed management. When a supplier makes a change, the oversight of those changes. 12:02 12:03 12:03
Our -- does the supplier perform. Do I actually receive materials on time. I mean, business performances. 12:03 12:03 12:03
There is various elements. Testing is only one of those elements. 12:03 12:03
Q. But the question I am asking is under what circumstances is a finished dose manufacturer acting reasonably in not testing all of the API -- API batches? 12:03 12:03 12:03 12:03
And -- and that doesn't have to do with whether or not the product is delivered on time. 12:03 12:03
A. Understood. 12:03
MR. STANOCH: Objection to form. 12:03
BY MS. LOCKARD: 12:03
Q. Okay. 12:03

Page 130

A. Understood. 12:03
So first and foremost, they have to 12:03
perform an identity test. It's an absolute 12:03
requirement. So that is one. They can't just not 12:03
test anything. 12:03
Secondarily, you have to qualify the 12:03
supplier in some way. 12:03
Normally that qualification is done 12:03
through some level of what is called "comparative 12:04
testing." So the supplier gives me a certificate of 12:04
analysis, and then I will also test the same batches 12:04
and do a comparative analysis. 12:04
That comparative analysis is then normally 12:04
repeated at periodic intervals to make sure that 12:04
they continue to have agreement using the same 12:04
methodology. So that is one aspect. 12:04
Normally I'll have a technical agreement 12:04
or what is called a "quality agreement" that will 12:04
identify "This is the way in which I will monitor 12:04
you in the future. You have responsibility for 12:04
these items." 12:04
I take assurances about those items, and 12:04
then I have the opportunity to have oversight of 12:04
that through periodic audits, data review, 12:04
evaluation of changes, notification of deviations or 12:04

Page 131

reprocessing, various elements that would be 12:04
outlined in that type of an agreement. 12:05
So all of that body of information 12:05
together then is input to a risk evaluation of the 12:05
supplier. And that risk evaluation of the supplier 12:05
contains other elements that are -- what is the 12:05
location of the supplier. 12:05
How much control do I have over the 12:05
supplier. 12:05
Do they have a lot of observations when I 12:05
go see them. 12:05
Are those observations when I run them 12:05
through the adulteration risk management approach, 12:05
do they rise high, are they mid-level, are they low. 12:05
What did FDA say about them. 12:05
What did other regulatory bodies say about 12:05
them if that information is available. 12:05
And then in that -- I can identify a 12:05
certain level of risk which will drive how much 12:05
scrutiny I use with that particular supplier. 12:05
Q. So let's just make sure that we're 12:05
understanding you. 12:05
A. Uh-huh. 12:05
Q. So the inputs that you say -- strike that. 12:06
Your opinion is that the inputs that are 12:06

Page 132

important to a finished dose manufacturer in 12:06
determining whether or not they must do their own 12:06
testing versus rely on the testing of their supplier 12:06
are these handful of items that you have just 12:06
listed. 12:06
Is that -- just as a premise, is that 12:06
fair? 12:06
A. Those are some of the items that most 12:06
manufacturers will employ that I have described. I 12:06
wouldn't say it's an exhaustive list. 12:06
Q. But those are the most important? 12:06
A. Those are the ones that come to mind. 12:06
Q. So one is "identity test." What do you 12:06
mean by that? 12:06
A. An ID test is the material comes in and 12:06
I -- through some validated testing I can say "This 12:06
is Valsartan." 12:06
Okay. So it's -- it's not an input. It's 12:07
a requirement. That comes from the regulation "Thou 12:07
shalt do ID testing." 12:07
You may do -- you may use or transcribe 12:07
information from the supplier's certificate of 12:07
analysis for other tests provided that you have 12:07
established the reliability of the supplier but 12:07
never for ID. That's just to make sure that the 12:07

Page 133

material is actually what it is. 12:07
Q. I understand. 12:07
A. From a safety perspective. So an ID test 12:07
must be performed. 12:07
Q. And in this case there is -- there's no 12:07
concern on your part about whether Teva was doing 12:07
the required identity test? 12:07
A. No. I didn't verify that they were doing 12:07
identity tests. But I had -- I don't have concerns 12:07
that they were not performing ID tests. 12:07
Q. Okay. So the second input that you 12:07
mentioned was the "comparative analysis." 12:07
A. Right. 12:07
Q. So by that, do you mean essentially taking 12:07
the -- the certificate of analysis results that are 12:08
provided by the -- by the supplier and then the 12:08
manufacturer doing some independent testing of the 12:08
same type of tests and then comparing those results 12:08
to see if they are the same or similar? 12:08
A. At a very high level, yes. That 12:08
compare -- comparison occurs often, though, or 12:08
frequently. 12:08
The first time I will have the same lots 12:08
and I'll look at their chromatography and my 12:08
chromatography. It's not just the result. They got 12:08

Page 134

.1, and I got .1. Well, that agrees. 12:08
Does the chromatography agree? Do I -- I 12:08
look at the actual graphic or the raw data. It 12:08
should look the same. This chromatography should 12:08
look similar to my chromatography provided that the 12:08
methods are similar. And the methods should be 12:08
similar. If they are not, there is a problem there 12:08
as well. 12:08
So that comparative analysis is then 12:08
performed on some routine basis. What I will then 12:09
do after that initial qualification -- it's 12:09
normally, like, an initial qualification when I 12:09
first start using the supplier. Then each time I 12:09
visit the supplier, I am going to do that evaluation 12:09
during audit. 12:09
I'm going to do -- I'm going to come with 12:09
a list of batches I have received, and I'm going to 12:09
look at the chromatography and see does it match 12:09
what I have tested my own -- you know, what I did 12:09
initial qualification, has anything changed. 12:09
If there is a change that occurs within 12:09
that period, I will need to repeat that comparative 12:09
analysis because it's a new process. 12:09
So it's a very rigorous oversight of data 12:09
review. 12:09

Page 135

This is where I find that Teva and Torrent 12:09
didn't necessarily within their audits -- when I 12:09
read an audit, it doesn't say, "Here are the lots I 12:09
reviewed and did comparative analysis." I'm looking 12:09
for that. 12:09
It doesn't -- it doesn't state that they 12:10
did this work. 12:10
So that's a -- not appropriate oversight. 12:10
Q. What is the -- you say periodic, but what 12:10
is the timetable for that? Is that annually? Is it 12:10
just at the audits, or what is the schedule in your 12:10
mind that -- that would be reasonable? 12:10
A. It's reasonable for a supplier in -- in 12:10
whatever frequency has been defined within their 12:10
technical agreement. 12:10
So there is, again, a regulation that says 12:10
every year you'll do comparative analysis. It's 12:10
generally done on some periodic basis. 12:10
I would say every six months, every year 12:10
some evaluation would be performed. 12:10
In the technical agreement, I may have the 12:10
opportunity to ask for a full data package. 12:10
Again, I'm not -- I can't state what 12:10
Teva's technical agreement or what the negotiations 12:10
were around that specifically. But I have the 12:10

Page 136

opportunity -- it's my data, my lot. I received it. 12:11
So I -- I also own the data. I can see it. 12:11
Normally it's on-site. 12:11
Certainly in every change. If you provide 12:11
me with a change or a notification of a change, that 12:11
should immediately trigger that comparative 12:11
analysis. Because I did comparative analysis to a 12:11
previous process. There is a new process now. So I 12:11
now need to repeat that comparative analysis. 12:11
Q. You agree, though, there's no regulation 12:11
that requires that this comparative analysis be done 12:11
on any interval; right? 12:11
MR. STANOCH: Objection. 12:11
THE WITNESS: I agree that the 12:11
21 CFR 210/211 do not have a detailed regulation that 12:11
says you need to do comparative analysis. 12:11
However, the industry standard -- and, 12:11
again, the "C" or the "Current" in Good Manufacturing 12:11
Practice, this is the standard practice that I see in 12:11
my experience throughout industry that comparative -- 12:12
there's no other way to establish the reliability of 12:12
test results if I don't look at any of the test 12:12
results. 12:12
So that's the standard way -- one of the 12:12
inputs. Again, one of the inputs for standard 12:12

Page 137

evaluation for reliability. 12:12
BY MS. LOCKARD: 12:12
Q. And I understand that you are testifying 12:12
based on industry standard. I just want to make 12:12
sure I'm not missing some cGMP regulation that says 12:12
you have to do this. 12:12
So there is no cGMP regulation that says 12:12
you have to do comparative analysis on some 12:12
schedule; right? 12:12
MR. STANOCH: Objection. Asked and 12:12
answered. 12:12
THE WITNESS: There -- there isn't a cGMP 12:12
regulation. But many firms will in their own 12:12
procedure base have a requirement to do comparative 12:12
analysis, and because they have it in their 12:12
procedures, it becomes GMP. 12:12
BY MS. LOCKARD: 12:12
Q. Do you agree that conducting supplier 12:12
audits every three years is within industry 12:12
standards? 12:12
A. I think it's long, personally. Drug 12:13
substance manufacturers are normally two years in 12:13
most firms. But, again, this is based on risk. 12:13
And the frequency of an audit is not based 12:13
on an established guideline but based on routine 12:13

Page 138

evaluation, yearly evaluation, and annual product review, which is part of the regulation to evaluate the supplier's risk and the general trends of what they are finding for that particular supplier of a drug substance. 12:13

So based on that evaluation that is required by the regulation on a yearly basis, I will change the risk profile of a supplier. And I might have to increase the frequency from three years to every six months or to every year based on whatever risk is coming from that supplier. It's a discretionary decision. 12:13

Q. The frequency of the audit is discretionary based on the circumstances? 12:13

A. It is. 12:14

Q. The -- the annual product review you mentioned, did you look at any annual product reviews for the Teva product? 12:14

A. I did not. 12:14

Q. Were any of those provided to you? 12:14

A. No. 12:14

Q. Did you ask for any of them? 12:14

A. No. 12:14

Q. Wouldn't that be an important input for you in your assessment of whether or not Teva was 12:14

Page 139

appropriately overseeing its supplier? 12:14

MR. STANOCH: Objection to form. 12:14

THE WITNESS: There are elements that were provided in production that give me the actual records. The annual product review is just a summary of the records I looked at. 12:14

So it's a summary report of things that I looked at. The summary report -- I can look at the actual direct records. That's what I looked at. 12:14

Audit reports. So an audit report is going to tell me -- I'm going to summarize that product in the annual summary review. 12:15

But I'm using the annual product review as a key point of when, as a minimum, I need to do this routine evaluation of suppliers. 12:15

It's certainly from regulation on an annual basis. 12:15

BY MS. LOCKARD: 12:15

Q. The annual product review is required by FDA regulation to assess the risk of the supplier providing that API. That is a -- that is a legal requirement that must be done; correct? 12:15

A. It's -- it's a statutory requirement. And it's not necessarily establishing whether the -- it summarizes the supplier's risk profile. 12:15

Page 140

Within supplier management, there should actually be a risk assessment of some sort for each individual supplier that has many inputs. Maybe not just the inputs that are required to be summarized in an annual product review. 12:15

The reason I mention annual product review is purely because that's the minimum frequency -- because it's required annually -- it's the minimum frequency where I would re-assess a supplier. 12:15

Q. But the annual product review is the one document that FDA actually legally requires a finished dose manufacturer complete for its suppliers in order to summarize the findings with respect to the supplier's risk. 12:16

A. It's a required document that will point them to the records that they need to see. 12:16

So FDA will routinely start with an annual product review because it points them to all the records for all the quality system elements that they are interested in, deviations, complaints, supplier management. Various elements. Validation. 12:16

It encompasses many different elements. 12:16

So it's a summary document, and it's to assist FDA in pointing to records that they'll go review. 12:16

The records that I speak of in my report 12:17

Page 141

are the underlying records for that summary report. 12:17

FDA just has an expectation that you are going to at least annually evaluate the risk of suppliers. 12:17

Q. When an -- when the FDA comes in to evaluate the finished dose manufacturer, it's your testimony that the first document they start with is the annual product review? That's what they look at first; right? 12:17

A. I -- 12:17

MR. STANOCH: Objection to form. 12:17

THE WITNESS: I didn't state that it's the first document they are going to look at. It's -- it's a document that they use as a guidance to other records. 12:17

In my experience, they do normally initially request annual product reviews. It's a helpful document for them. 12:17

But, certainly, if they choose not to approach the audit that way, I can't say specifically that they are even always going to look at an annual product review. 12:17

But it is a document, because it is a regulatory requirement, a compliance requirement, that they would normally review. Most EIRs I read will identify some annual product review. 12:17 12:18

Page 142

So when I say it's one of the first 12:18
documents, it's the best -- one of the best, in my 12:18
opinion, summary documents that points to all the 12:18
records that they want to see. 12:18
They also want to see if you are doing it 12:18
because many firms struggle with producing annual 12:18
product reviews on time. 12:18
BY MS. LOCKARD: 12:18
Q. So just to clarify on the record, you said 12:18
so FDA -- [as read]: 12:18
"The FDA review will start with an 12:18
annual product review because it points 12:18
them to all the records for all the 12:18
quality system elements they are 12:18
interested in, deviations, compliance, 12:18
supplier management." 12:18
That was your testimony just a few minutes 12:18
ago. 12:18
A. And -- 12:18
MR. STANOCH: Objection. 12:18
THE WITNESS: I'll restate then that I 12:18
apologize for saying it's the first thing. I can't -- 12:18
I can't state what every FDA investigator is going to 12:18
do for the first document they look at. 12:18
What I do find is this -- this is one of the 12:19

Page 143

source documents that FDA relies upon for those 12:19
records. So I'll clarify my testimony in that way. 12:19
BY MS. LOCKARD: 12:19
Q. You also said [as read]: 12:19
"So when I say it's one of the first 12:19
documents, it's the best -- one of the 12:19
best, in my opinion, summary documents 12:19
that points to all the records they 12:19
want to see." 12:19
That was your testimony just minutes ago; 12:19
correct? 12:19
A. I agree with that. 12:19
MR. STANOCH: Objection. 12:19
BY MS. LOCKARD: 12:19
Q. And yet even though it is one of the best 12:19
documents for FDA to review, you didn't even look at 12:19
those documents for Teva -- 12:19
MR. STANOCH: Well, objection. 12:19
BY MS. LOCKARD: 12:19
Q. -- correct? 12:19
MR. STANOCH: Objection to form. Misstates 12:19
prior testimony. 12:19
THE WITNESS: So I, again, said previously 12:19
that I didn't look at annual product reviews because I 12:19
am looking at the source records. I looked at a 12:19

Page 144

change control. I didn't look at the summary of 12:19
change controls from the annual product review. I 12:19
have the change control. I have the direct record. 12:20
What is a called a "primary GMP record." 12:20
The annual product review is a secondary 12:20
report. It points to primary -- what is called 12:20
"statutory records." There's a change control. A 12:20
change control is a required record. 12:20
A batch record is a required record. 12:20
The batch record information will get 12:20
summarized in an annual product review, while the 12:20
batch record may have that information. 12:20
Again, for the purposes of this report and 12:20
what I opined on here, I am looking at supplier 12:20
quality records, change controls, audit reports, the 12:20
items that I have listed in my -- my materials 12:20
considered. 12:20
Annual product reviews are just a summary of 12:20
those records. It wouldn't be -- so I didn't look at 12:20
them. I looked at the actual primary GMP record. 12:20
BY MS. LOCKARD: 12:20
Q. Would you expect the annual product 12:20
reviews to include information about the frequency 12:20
of Teva's testing of the ZHP API? 12:20
MR. STANOCH: Objection to form. 12:21

Page 145

THE WITNESS: No. Would not be a requisite 12:21
section within an APR. 12:21
BY MS. LOCKARD: 12:21
Q. Is it your belief that you have reviewed 12:21
all of the source documents which would be 12:21
summarized in Teva's annual product reports? 12:21
A. No. No. Because an annual product report 12:21
covers all elements of the manufacturer of a 12:21
product. I have opined on primarily laboratory 12:21
controls and the supplier management program. 12:21
Q. You mentioned when we were talking about 12:21
the handful of inputs that go into a decision -- 12:21
making a reasonable decision about the frequency of 12:21
testing, the API's supplier products, one of the 12:21
things you mentioned was the location of the 12:21
supplier. 12:21
Do you remember that? 12:21
A. Yes. 12:21
Q. What did you mean by that? 12:21
A. Geographical location is a risk concern in 12:21
the industry. Manufacturers who are abroad are 12:21
difficult -- more difficult to manage and to provide 12:22
oversight than those that are domestic. 12:22
Again, my experience in the industry is 12:22
there are more compliance concerns abroad. So in 12:22

Page 146

many of the programs that I have promulgated to clients a key risk category is geography. 12:22
Certain geographies are known to have more compliance issues than others. 12:22
Again, this is a discretionary tool. And it's a tool I recommend to clients is to include relative geography as that detection indicator in ICH Q9, "How well can I detect problems coming from the supplier." It's more difficult with suppliers that are abroad. 12:22
Q. Are there any FDA guidances or pronouncements that -- that determine that certain geographical locations are required -- require higher surveillance or -- or higher oversights than others? 12:23
A. No. There are no FDA regulations on that. It's based on regulatory surveillance. 12:23
For my experience going off and looking at numbers warning letters, types and severity of issues that are identified by FDA by categories in different geographies, that there is problems with data integrity abroad. There is problems with various understandings of the cGMP and the underlying concepts of cGMP. 12:23
And I work a lot with companies abroad. I

Page 147

have direct experience with Chinese firms, Indian firms, and their relative compliance. 12:23
Again, it's discretionary. So I recommend that geography be a -- one of the risk inputs associated with applying that -- or managing suppliers. 12:24
Q. And I understand your view on that. But that's not stated anywhere officially by FDA? 12:24
A. No, it's not. 12:24
Q. So you -- you would not, I assume, recommend to your -- to your clients that they not use firms that are abroad for API supply? 12:24
A. Absolutely not. No. So there's no concern of using a supplier who is abroad. Most of the drug supply chain comes from abroad. So there's no concern there. And I would never make a recommendation generally. 12:24
But there may be certain manufacturers that it's higher risk. 12:24
And, again, this is from a compliance perspective -- is an extremely high-risk area. So how much risk do you want to take. 12:24
And then if you are going to take that high risk, what will be your interim controls and mitigation plan to reduce that risk as the guidances 12:24

Page 148

require on ICH Q9. 12:25
Q. So in Teva's circumstances, if they have suppliers, one from abroad and one from the U.S., is it your view that they would need to employ greater surveillance or oversight over the non-U.S. supplier than they do the U.S. supplier? 12:25
MR. STANOCH: Objection to form. Incomplete hypothetical. 12:25
Go ahead. 12:25
THE WITNESS: In my experience, I make that recommendation to clients based on my experience. That is purely my experience. 12:25
BY MS. LOCKARD: 12:25
Q. Your recommendation to your clients is more oversight if you have a supplier abroad compared to suppliers who are domestic? 12:25
A. It is. 12:25
MR. STANOCH: Same objection. 12:25
BY MS. LOCKARD: 12:25
Q. The quality agreement you mentioned -- let me just -- there is a... 12:25
MR. STANOCH: Counsel, you want to take a break? It's been a couple of hours anyway. If you are shifting to a document you need to find... 12:26
MS. LOCKARD: I -- I -- if you would like

Page 149

to, I would be happy to. 12:26
MR. STANOCH: Mr. Russ? 12:26
THE WITNESS: Yes, please. 12:26
MR. STANOCH: Okay. Yeah. 12:26
THE VIDEOGRAPHER: Okay. Going off record at 12:27 p.m. 12:26
(At the hour of 12:27 p.m. a luncheon recess was taken. The deposition was resumed at 1:36 p.m., the same persons being present.)

Page 150

LOS ANGELES, CALIFORNIA
THURSDAY, JANUARY 5, 2023
1:36 P.M.
13:36
THE VIDEOGRAPHER: And we are back on the 13:36
record at 1:36 p.m. Start of Media Number 5. 13:36
13:36
EXAMINATION (CONTINUED) 13:36
BY MS. LOCKARD: 13:36
Q. Okay. Mr. Russ, we'll get going here. 13:36
MS. LOCKARD: Is everybody good on the call? 13:36
Okay. 13:36
BY MS. LOCKARD: 13:36
Q. All right. So in your report and in the 13:36
materials reviewed, you saw some correspondence 13:36
between ZHP and Novartis about Novartis's discovery 13:36
of unknown peaks that led to the discovery of the 13:36
nitrosamine; correct? 13:36
A. Correct. 13:36
Q. Do you have any understanding who -- what 13:36
Novartis's role is just generally in the marketplace 13:37
for Valsartan? 13:37
A. I -- I believe that they are the innovator 13:37
for Valsartan. So I guess they are the owner of 13:37
Diovan. 13:37

Page 151

And I guess they were searching for 13:37
additional supply of drug substance from ZHP. 13:37
Q. So are you -- you are guessing that they 13:37
were searching for additional supply, or did you see 13:37
documentation as to why they had obtained it? 13:37
A. Yeah. So they are coordinating a 13:37
supplier -- a material qualification with ZHP. So 13:37
that tells me that they are adding ZHP or -- 13:37
potentially or considering ZHP as a supplier of 13:37
Valsartan. 13:37
Q. Did -- did you see any documentation in 13:37
the case anywhere that Novartis was actually 13:37
implementing a plan to commercialize Valsartan using 13:37
ZHP API? 13:38
A. Not an email or something that directly 13:38
says that, that I recall. It may be in the 13:38
production. But certainly the correspondence 13:38
between ZHP and Novartis indicates that they are 13:38
qualifying material. And I assume for 13:38
commercialization use. 13:38
Q. In your experience in the industry have 13:38
you ever heard of a brand performing analysis or 13:38
testing on a competitor's product? 13:38
A. Some firms will reverse engineer 13:38
another -- another company's products. I have heard 13:38

Page 152

of that. Yes. 13:38
Q. So is that one potential as well in terms 13:38
of the realms of possibilities as to why ZHP's API 13:38
may have been being assessed by Novartis? 13:38
MR. STANOCH: Objection to form. 13:39
THE WITNESS: I couldn't comment on that. 13:39
BY MS. LOCKARD: 13:39
Q. Have you ever spoken to anyone at 13:39
Novartis? 13:39
A. No. Not in regard to this matter, no. 13:39
Q. Have you seen any of Novartis's quality 13:39
documentation? 13:39
A. Not the documentation. Only the email 13:39
correspondence or the requests for information 13:39
and -- and whatever information was in those 13:39
documents. 13:39
Q. Just what was in ZHP's production is what 13:39
you reviewed? 13:39
A. Correct. 13:39
Q. You haven't reviewed any documents that 13:39
were actually provided by Novartis; correct? 13:39
A. I have Novartis documentation -- or 13:39
documentation about Novartis. As far as the source, 13:39
that I couldn't tell you as well. I would have to 13:39
look at the production or someone could tell me from 13:39

Page 153

the production whether it came from Novartis or if 13:39
it came from ZHP. 13:39
Q. Have you ever seen any documentation in 13:39
the case suggesting that Novartis brand drug Diovan 13:39
may have been found to contain the presence of the 13:39
nitrosamine impurity? 13:40
MR. STANOCH: Objection to form. 13:40
THE WITNESS: Again, I couldn't comment 13:40
directly that I have in my mind or remember a specific 13:40
document that points to Diovan. 13:40
BY MS. LOCKARD: 13:40
Q. Did you ever ask the question of counsel 13:40
whether the brand drug itself also was found to 13:40
contain the impurity? 13:40
MR. STANOCH: Objection to form. 13:40
THE WITNESS: I didn't ask. And it wasn't 13:40
germane to my report or what I opined on. It had 13:40
nothing to do with whether Diovan contained 13:40
nitrosamine, nothing to do with what I was -- you 13:40
know, asked to do. 13:40
BY MS. LOCKARD: 13:40
Q. So it doesn't change your opinion in any 13:40
way if you assume the brand Valsartan also contained 13:40
the NDMA impurity? 13:40
A. No, it wouldn't. 13:40

Page 154

Q. One of the components about Good Manufacturing Practices that we were talking about before the break related to quality agreements. Did you see quality agreements between ZHP and Teva in your review of the material produced in the case? 13:40 13:41 13:41 13:41 13:41

A. Yes. 13:41

Q. Okay. Did you have criticisms about content of those quality agreements? 13:41 13:41

A. No. 13:41

Q. Is there a cGMP reg, statute, or otherwise that requires a written quality agreement between the API supplier and a finished dose? 13:41 13:41 13:41

A. No. 13:41

MR. STANOCH: Objection to form. 13:41

THE WITNESS: Sorry. 13:41

MR. STANOCH: It's okay. 13:41

THE WITNESS: No. There is guidance currently on -- from FDA on the benefits and value of a quality agreement or technical agreement. But it's -- no. It's not required by a regulation specifically. 13:41 13:41 13:41 13:41 13:41

BY MS. LOCKARD: 13:41

Q. And is that the guidance that you referenced in your report? 13:41 13:41

Page 155

A. It is. 13:41

Q. Okay. Let's take a look at that. 13:42

MS. LOCKARD: This is going to be Exhibit Number 11. 13:42 13:42

(Deposition Exhibit 11 was marked for identification and is attached hereto.) 13:42 13:42

BY MS. LOCKARD: 13:42

Q. All right. And this is referenced in Footnote 17 to your report. 13:42 13:42

A. It is. 13:42

Q. So if you turn with me to the Introduction. Again, being a guidance, the Introduction states that [as read]: 13:42 13:42 13:42

"This guidance describes FDA's current thinking on defining, establishing, and documenting manufacturing activities of the parties involved in contract drug manufacturing subject to current good manufacturing [...] requirements." 13:42 13:42 13:42 13:42 13:42 13:42 13:42

Do you see that? 13:42

A. Yes. 13:42

Q. This guidance itself, you would agree, applies to contract manufacturing; right? 13:43 13:43

A. It does. But it -- it's applied also to the general supply base as well. Technical and quality agreements are used broadly today in the industry to define relationships between suppliers and contract manufacturers. 13:43 13:43 13:43 13:43 13:43 13:43 13:43 13:43

Page 156

Q. And I understand that your position is the industry standard requires a quality agreement, but this document itself doesn't say anything anywhere about quality agreements with suppliers, does it? 13:43 13:43 13:43 13:43

A. Not specifically. One would expect that Teva has quality agreements and requires quality agreements in their procedures. 13:43 13:43 13:43

Q. So on the last paragraph of the Introduction, it says [as read]: 13:43 13:43

"In particular, we describe how parties involved in contract drug manufacturing can use quality agreements to delineate their manufacturing activities to ensure compliance with CM -- CGMP." 13:43 13:43 13:43 13:43 13:44 13:44

So, again, it's discretionary based on this guidance. It's not required; right? 13:44 13:44

MR. STANOCH: Object to the form. 13:44

THE WITNESS: You are correct in what the document says. I'm just stating that the way that this document is used in the industry is broadly, and 13:44 13:44 13:44

Page 157

that the entire supply base quality agreements are used broadly across the supply base. 13:44 13:44

I'm also not, within the report, identifying any inconsistencies or problems that identified with the technical agreement. 13:44 13:44 13:44

BY MS. LOCKARD: 13:44

Q. On the -- Page 2, last paragraph before the Section 2. 13:44 13:44

A. Yes. 13:44

Q. And this -- this harkens back to our discussion earlier, but this document says [as read]: 13:44 13:44 13:44

"In general FDA's guidance documents do not establish legally enforceable responsibilities." 13:44 13:44 13:44

You agree with that? 13:44

A. I agree that that's what it says. Yes. 13:44

Q. And on the last sentence of that paragraph [as read]: 13:44 13:44

"The use of the word should in Agency guidances means that something is suggested or recommended, but not required." 13:45 13:45 13:45 13:45

Agree with that? 13:45

A. I agree that that's what is being read 13:45

Page 158

there. 13:45
But, again, the way industry uses these 13:45
documents is different than what that description 13:45
is. 13:45
Q. So in your review of the -- of the quality 13:45
agreements between ZHP and Teva, you did not find 13:45
any deficiencies in the content of those; is that 13:45
correct? 13:45
A. No. I didn't find any specific deficiency 13:45
in the technical agreement itself. 13:45
Q. So just to make sure that we are on the 13:45
same page -- 13:45
MS. LOCKARD: So we'll mark this as 13:45
Exhibit 12, please. 13:45
(Deposition Exhibit 12 was marked for 13:45
identification and is attached hereto.) 13:45
BY MS. LOCKARD: 13:45
Q. You can put that one aside. This is Bates 13:45
Number TEVA -212. 13:45
Is this one of the quality agreements you 13:46
reviewed? 13:46
A. It appears to be. It looks like the 13:46
quality agreement I reviewed. Yes. 13:46
Q. Okay. This appears to be the agreement 13:46
between Arrow Pharm and ZHP dated 2011. 13:46

Page 159

Do you see that? 13:46
A. I do. 13:46
Q. And so this quality agreement would have 13:46
been in effect at the time of the change control; 13:46
right? 13:46
A. Yes. It appears so. 13:46
Q. Okay. And this agreement on Page 4 13:46
provides for routine auditing of the supplier; 13:46
right? 13:46
A. Sorry. On page -- I have Page 3. But... 13:46
Q. Oh. Correct. On this one it's on Page 3. 13:46
A. Oh. Okay. 13:46
Q. It does -- it does have a provision on 13:46
Page 3 for routine audits, though. 13:46
A. Yes. 13:46
Q. And that's what you would expect from a 13:46
reasonable and prudent manufacturer; correct? 13:46
A. Yes. Yeah. 13:46
MR. STANOCH: Ob- -- 13:46
THE WITNESS: That you end up doing audits, 13:46
for sure. 13:46
MS. LOCKARD: Okay. This will be Exhibit 13:47
Number 13. 13:47
(Deposition Exhibit 13 was marked for 13:47
identification and is attached hereto.) 13:47

Page 160

BY MS. LOCKARD: 13:47
Q. This is Bates Number -20279, TEVA. 13:47
Have you seen this document before? 13:47
A. Yes. 13:47
Q. Okay. This is an agreement between 13:47
Actavis and ZHP dated 2016; correct? 13:47
A. I don't see a date -- oh. Yeah. The date 13:47
of issuance, but if it was approved that date, I 13:47
don't see. 13:47
I'll stipulate it is, yes. 13:47
Q. Okay. And there are signatures on the 13:47
back that are dated 2016 if you -- 13:47
A. Yes. Okay. 13:47
Q. Okay. So this agreement, you would agree, 13:47
would have been in place at the time of the 13:47
discovery of the nitrosamine impurity and the 13:47
recall? 13:47
A. Agreed. 13:47
Q. And this -- this document also permits 13:47
Actavis to audit ZHP routinely; right? 13:47
A. Yes. 13:48
Q. Okay. And at one point -- it sounds like 13:48
a few minutes ago you referred to a technical 13:48
agreement. And there -- there is also a quality 13:48
technical agreement between Actavis and ZHP. 13:48

Page 161

Did you see that? 13:48
A. Yes. I believe so. I apologize for 13:48
semantics. Quality agreements, technical 13:48
agreements, supply agreement all kind of refer to 13:48
the same type of vehicle. 13:48
MS. LOCKARD: Okay. So let's mark this one 13:48
as Exhibit 13. 13:48
THE REPORTER: 14. 13:48
MS. LOCKARD: 14. 13:48
THE REPORTER: Yes. 13:48
(Deposition Exhibit 14 was marked for 13:48
identification and is attached hereto.) 13:48
BY MS. LOCKARD: 13:48
Q. All right. And this is Bates -2213 for 13:48
Teva. 13:48
And is this the technical agreement you 13:48
reviewed? 13:48
A. Yes. Yes. 13:48
Q. Okay. And you don't have any criticisms 13:48
of the content of any of these quality or technical 13:49
agreements? 13:49
A. I do not. No. They are all standard 13:49
tech -- kind of template approaches to delineating 13:49
responsibilities. 13:49
Q. Did you review any of Teva's quality 13:49

Page 162

policies in your review of the case? 13:49
A. If they were provided to me. I can't 13:49
recall specifically. I didn't reference any of 13:49
those in my report. They were provided in the 13:49
production. And I reviewed them, and I opened them 13:49
and took a look at them. 13:49
MS. LOCKARD: Well, let's -- we'll mark this 13:49
as... 13:49
MR. HARKINS: 15. 13:49
MS. LOCKARD: 15. 13:49
(Deposition Exhibit 15 was marked for 13:49
identification and is attached hereto.) 13:49
MS. LOCKARD: How come I only have -- I only 13:49
have copies of this. But... 13:49
BY MS. LOCKARD: 13:49
Q. So this is -- do you believe you reviewed 13:49
this document now that you look at it? 13:49
A. Again, if I have listed it in my -- 13:50
my considered -- my documents considered, I didn't 13:50
use it in the reports. So I may not. 13:50
I certainly had it if it was provided to 13:50
me in production and I had it listed on my materials 13:50
considered. 13:50
Q. Well, I'll represent -- and we can check 13:50
it if you want, but I did not see that listed on 13:50

Page 163

your reliance list. 13:50
A. Okay, then. Then -- this looks like a 13:50
very standard policy document. Again, it doesn't 13:50
look extremely familiar to me. 13:50
Q. Okay. As part of your review, you have 13:50
not generated any criticisms of Teva's policies -- 13:50
is that fair? -- written policies? 13:50
MR. STANOCH: Objection to form. 13:50
Go ahead. 13:50
THE WITNESS: No. And I haven't stated as 13:50
such in my report as well. 13:50
BY MS. LOCKARD: 13:50
Q. Okay. And just so I get a clean question. 13:50
You know, as you sit here today, you have 13:50
not generated any opinions critical of Teva's 13:50
written policies with respect to their quality 13:51
system; correct? 13:51
MR. STANOCH: Objection to form. 13:51
THE WITNESS: No. 13:51
BY MS. LOCKARD: 13:51
Q. "No," that is correct? 13:51
A. No. Yeah. No, I haven't criticized the 13:51
policies from Teva. 13:51
MR. STANOCH: Same objection. 13:51
///

Page 164

BY MS. LOCKARD: 13:51
Q. Okay. So with respect to their quality 13:51
processes in their audit program with ZHP, do you 13:51
have criticisms about how the audits were conducted? 13:51
A. I do have criticisms that they don't 13:51
appear to list within the summary of audit reports 13:51
that they specifically looked at documents one would 13:51
expect them to look at, which is the analytical 13:51
data -- at least the statistically significant 13:51
sample of the analytical data that supports the 13:51
batches that they received from ZHP during that time 13:51
frame. 13:51
So that's absent, which is a -- something 13:51
they should review while on-site for an audit. 13:52
That's the purpose of the audit, actually. One of 13:52
the purposes of the audit. 13:52
Q. Did you review the audit reports we 13:52
produced related to the ZHP audits? 13:52
MR. STANOCH: Objection to form. 13:52
THE WITNESS: Yes. 13:52
BY MS. LOCKARD: 13:52
Q. Okay. And so in reviewing these reports, 13:52
you did not find any evidence that -- that the Teva 13:52
auditors had reviewed the analytical data and the 13:52
chromatograms. 13:52

Page 165

Is that the basis -- is that the gist of 13:52
the opinion? 13:52
MR. STANOCH: Objection to form. 13:52
THE WITNESS: I -- I didn't see lists of 13:52
documents reviewed that show specific batches of drug 13:52
substance that they -- that Teva received that they 13:52
reviewed. 13:52
BY MS. LOCKARD: 13:52
Q. Did you have any other concerns or 13:52
criticisms about the content of the audit reports? 13:52
MR. STANOCH: Objection to form. 13:52
THE WITNESS: The only other consideration I 13:52
would expect to see within the audit reports is that 13:52
any declarations that are made by the supplier -- 13:52
these are declarations of absence of certain types of 13:53
deleterious materials or any of those types of 13:53
things -- that there is a verification of those 13:53
statements during the audit that support for any 13:53
general statements that are made by the supplier in 13:53
the technical package. 13:53
BY MS. LOCKARD: 13:53
Q. So did you not see any certifications from 13:53
ZHP in the Teva production indicating that Teva was 13:53
certifying the API had no carcinogenic impurities? 13:53
A. Teva was certifying? Or... 13:53

Page 166

Q. Excuse me. Let me restate that. 13:53
Did you not see any certifications by ZHP 13:53
contained in the Teva production indicating that the 13:53
ZHP API had no carcinogenic impurities? 13:53
A. I didn't see within -- what I am stating 13:53
is I didn't see within the audit reports that any 13:53
auditor verified any such statements that may have 13:54
been made and provided to Teva. 13:54
Q. But you did see in the production, 13:54
including in the ANDAs, where the certifications of 13:54
the absence of deleterious impurities were provided? 13:54
MR. STANOCH: Objection to form. 13:54
THE WITNESS: Again, if it's within the 13:54
materials that were considered, those statements were 13:54
there. These are general -- these statements are 13:54
ubiquitous. 13:54
What I am looking for specifically is that 13:54
there is some verification of those statements within 13:54
the audit reports. 13:54
You asked me originally did I have concerns 13:54
with the audit reports. That's my concern with the 13:54
audit reports. 13:54
BY MS. LOCKARD: 13:54
Q. Okay. And so that concern -- in order to 13:54
remedy that, what would have to be in that audit 13:54

Page 167

report? An actual certification from ZHP? 13:54
A. No. Just a reference to the quality 13:54
records that were reviewed that support those 13:54
statements by the auditor. 13:55
That it would be in a materials 13:55
considered -- you know, a list of documents reviewed 13:55
during the audit, or that there would be texts 13:55
summarizing that their review was complete of those 13:55
types of documents that support statements. 13:55
Again, statements in applications and 13:55
statements provided in technical packages -- again, 13:55
trust but verify. Get a statement from the supplier 13:55
upon the audit visit. I'll verify what quality 13:55
records support statements that have been made. 13:55
Q. And did you find the -- the timing -- the 13:55
timing of the audits of ZHP by Teva to be within the 13:55
reasonable time frame? 13:55
A. Yes. 13:55
MR. STANOCH: Objection. 13:55
THE WITNESS: I'm sorry. 13:55
MR. STANOCH: Objection. 13:55
Go ahead. 13:55
THE WITNESS: They appear to be reasonable. 13:55
BY MS. LOCKARD: 13:55
Q. Okay. I'm not going to attach all the 13:55

Page 168

audit reports if it's not necessary. 13:55
So would you -- during those audits of 13:56
ZHP, would you expect the auditor to conduct the 13:56
type of analysis that led Novartis to identify the 13:56
NDMA substance in the Valsartan API? 13:56
A. No. 13:56
Q. Turning to your -- your report which -- if 13:56
you have before you. 13:56
A. Uh-huh. 13:56
Q. At the top of Page 9 -- and this is a 13:57
quotation, I believe, from the NDA guidance. 13:57
But you have quoted at the bottom of that 13:57
quote [as read]: 13:57
"The finished drug product 13:57
manufacturer should also ensure that 13:57
compendial-grade APIs comply with 13:57
compendial specifications." 13:57
Do you see that? 13:57
A. Yeah. This is -- I do see that. 13:57
This is a statement from the questions and 13:57
answers, I believe. This is not the guidance but 13:57
Exhibit 10. 13:57
Q. Okay. So is it your understanding that 13:57
the -- that the Valsartan produced by Teva complied 13:58
with all the applicable compendial specifications? 13:58

Page 169

MR. STANOCH: Objection. 13:58
THE WITNESS: The material -- there is a 13:58
compendial monograph for Valsartan. Teva identifies 13:58
their -- Valsartan as U.S. -- what is called "USP" or 13:58
"United States Pharmacopeia" on the labeling. It 13:58
would be incumbent upon them to assure compliance with 13:58
the compendial specifications. 13:58
BY MS. LOCKARD: 13:58
Q. And you haven't seen any evidence in the 13:58
documentation that Teva's product did not comply 13:58
with the compendial specifications; right? 13:58
A. No. I don't have issue with Teva's 13:58
compliance to compendial specifications for 13:58
Valsartan they received. 13:58
MS. LOCKARD: So let's mark this as 13:58
exhibit... 13:58
THE REPORTER: 16. 13:59
(Deposition Exhibit 16 was marked for 13:59
identification and is attached hereto.) 13:59
BY MS. LOCKARD: 13:59
Q. All right. Is this -- what is this? Do 13:59
you recognize this document? 13:59
A. [Witness reviews document]. 13:59
Yeah. This is the USP-NF Online monograph 13:59
for Valsartan drug substance. 13:59

Page 170

Q. Okay. And if you go to Page 2 of that document, you'll see where it has "Acceptance Criteria"? 13:59
A. Yes. 13:59
Q. And it does not include any NDMA or NDEA nitrosamines; correct? 13:59
A. It does not. 13:59
Q. It says [as read]: 13:59
"Any other individual impurity at .1." 13:59
Is that right? 13:59
A. That is correct. 13:59
Q. And that means that percentages below .1 are acceptable? 13:59
MR. STANOCH: Objection. 13:59
THE WITNESS: It -- it means that percentages below .1 would not need to -- to be evaluated against whether or not they meet the compendial specification or the internal specification. 13:59 14:00 14:00
But the presence of peaks, even below .1 percent that are not expected to be in the chromatography, should be questioned. 14:00 14:00 14:00
BY MS. LOCKARD: 14:00
Q. But this doesn't require any -- other than questioning the peaks, this does not require any further action as long as you are within that limit? 14:00 14:00

Page 171

MR. STANOCH: Objection to form. 14:00
BY MS. LOCKARD: 14:00
Q. Is that right? 14:00
A. It doesn't -- 14:00
MR. STANOCH: Same objection. 14:00
THE WITNESS: -- require an investigation to be immediately opened for out of specification. 14:00 14:00
There's another type of investigation called an "Out of Trend." Something that meets specification but is odd or different that should be investigated as a trend. 14:00 14:00 14:00
BY MS. LOCKARD: 14:00
Q. Right. 14:00
And in this case, there's no evidence that -- excuse me -- that Teva noticed anything that qualified as an Out of Trend that needed to be further investigated. 14:00 14:01 14:01
MR. STANOCH: Objection. 14:01
BY MS. LOCKARD: 14:01
Q. Is that right? 14:01
A. They didn't notice it because they didn't test anything. So they didn't have any chromatography. So if they didn't have any 14:01 14:01 14:01

Page 172

chromatography -- I can't find a penny that I lost if I don't look for a penny that I lost. 14:01 14:01
Q. Okay. Well, I just want to make sure I understand your opinions. 14:01 14:01
A. No. 14:01
Q. There is nothing that Teva -- there is no evidence in Teva's records that there was an Out of Trend report that they failed to act on; right? 14:01 14:01 14:01
MR. STANOCH: Objection. 14:01
Go ahead. 14:01
THE WITNESS: What is -- what my concern is, is that there isn't anything in the record that shows that Teva evaluated chromatography for the drug substance they were receiving from ZHP. 14:01 14:01 14:01 14:01
BY MS. LOCKARD: 14:01
Q. I understand your concern being that, from your review, you don't feel that Teva did an adequate review of the chromatography. 14:01 14:02 14:02
But my question to you is, based on what is in the documentation, you found nothing to suggest Out of Trend results; right? 14:02 14:02 14:02
MR. STANOCH: Objection. 14:02
THE WITNESS: I didn't find an Out of Trend investigation around peaks in the chromatography, no. 14:02 14:02
///

Page 173

MS. LOCKARD: This we'll mark as the next exhibit. 14:02 14:02
THE REPORTER: 17. 14:02
MS. LOCKARD: 17. This would be -- 14:02
(Deposition Exhibit 17 was marked for identification and is attached hereto.) 14:02 14:02
BY MS. LOCKARD: 14:02
Q. Well, are you familiar with this document as well? 14:02 14:02
A. Yeah. This is the -- this is for the drug product. 14:02 14:02
This is for the drug substance [witness indicates document]. 14:02 14:02
This is for the drug product [witness indicates document]. 14:02 14:02
Q. And, again, on Page 2 it has "Acceptance Criteria," and that list also does not reference NDMA or NDEA; correct? 14:02 14:02 14:02
MR. STANOCH: Objection. 14:02
THE WITNESS: Correct. 14:02
BY MS. LOCKARD: 14:02
Q. And it discusses each individual impurity with a limit of .2 percent; right? 14:02 14:02 14:02
A. It appears so. 14:02
Q. And so anything below .2 percent would be 14:02

Page 174

considered acceptable; correct? 14:03
MR. STANOCH: Objection to form. 14:03
BY MS. LOCKARD: 14:03
Q. Correct? 14:03
MR. STANOCH: Same objection. 14:03
THE WITNESS: Again, you are saying 14:03
acceptable. It's -- meets specification does not 14:03
necessarily mean that it's acceptable. Should it be 14:03
present in the chromatography is the question. Not 14:03
whether it meets spec. 14:03
MR. STANOCH: And for the record, Counsel, I 14:03
assume you highlighted the portion here on Page 2? 14:03
MS. LOCKARD: I didn't. 14:03
Did you? 14:03
MR. HARKINS: I didn't. 14:03
MR. STANOCH: Same thing on prior the 14:03
exhibit, the highlighting of Footnote C. 14:03
MS. LOCKARD: But I'll stipulate that it's 14:03
likely not in the original. 14:03
MR. STANOCH: That's fine. Thanks, Counsel. 14:03
BY MS. LOCKARD: 14:03
Q. And on this document, in fact, it says, 14:03
under "Acceptance Criteria" to [as read]: 14:03
"...disregard any peak due to 14:03
Valsartan related Compound B and any 14:03

Page 175

peaks less than or equal to 14:03
.05 percent." 14:03
Do you see that? 14:03
A. I do. 14:03
Q. So in terms of the peaks -- assuming that 14:04
Teva had evaluated that the chromatographs had found 14:04
peaks that are present, do you have opinions about 14:04
whether those peaks have to reach a certain size, 14:04
shape, width in order to be in the category of 14:04
requiring follow-up or questions, as you said? 14:04
MR. STANOCH: Objection to form. 14:04
Go ahead. 14:04
THE WITNESS: I don't have any concerns as 14:04
it relates to the drug product. I do have concerns as 14:04
it relates to the drug substance, but not the drug 14:04
product. No. 14:04
BY MS. LOCKARD: 14:04
Q. Even on the drug substance when looking at 14:04
unknown peaks, the presence of an unknown peak is a 14:04
common problem; correct? 14:04
MR. STANOCH: Objection. 14:04
THE WITNESS: No. It's not a common 14:04
problem. It's a unique problem. 14:04
BY MS. LOCKARD: 14:05
Q. So you'd disagree with the statement that 14:05

Page 176

the presence of an unknown peak is a common problem? 14:05
MR. STANOCH: Objection. 14:05
THE WITNESS: In my experience, it is not 14:05
common. 14:05
What is common? Frequently? Once a week? 14:05
Twice a week? Once a month? Every batch? There's no 14:05
qualifier to that. 14:05
Certainly, unknown peaks in chromatography 14:05
are very concerning; and, in my experience, they don't 14:05
happen frequently. So something that is common 14:05
doesn't sound as if that is something I agree to. 14:05
BY MS. LOCKARD: 14:05
Q. Well, if you'll turn to Page 60 [verbatim] 14:05
of your report. 14:05
A. What paragraph are you on? 14:05
Q. It's -- excuse me. I'm sorry. Page 11, 14:05
Paragraph 60. 14:05
A. I didn't think I had 60 pages. 14:05
Q. Wasn't that long. 14:05
Are you there with me at Paragraph 60? 14:05
A. Yes. 14:06
Q. And the -- the third sentence of your 14:06
report says [as read]: 14:06
"While the presence of an unknown 14:06
peak is a common problem, it can be 14:06

Page 177

caused by many things which can range 14:06
from simple sample preparation 14:06
contamination all the way to unexpected 14:06
and potential genotoxic impurities in 14:06
API." 14:06
Were those your words? 14:06
A. They are my words, yes. 14:06
Q. Okay. So do you agree with your report 14:06
that -- 14:06
A. I do agree with my report. 14:06
Q. -- "the presence of an unknown peak is a 14:06
common problem"? 14:06
MR. STANOCH: Objection. You have the rest 14:06
of the sentence. 14:06
Go ahead. 14:06
THE WITNESS: Yeah. I agree that it's a 14:06
problem that we have to deal with. When I meant 14:06
"common," I didn't mean frequent. I meant that this 14:06
is a problem that the industry needs to deal with. 14:06
BY MS. LOCKARD: 14:06
Q. And you do say -- 14:06
A. It's not -- it's not unique in that no one 14:06
in the industry has ever dealt with this problem 14:06
before. 14:06
Q. You do say that peaks can be caused by 14:06

Page 178

many things, including simple sample preparation contamination; right? 14:06
A. Yes. 14:07
Q. And so is -- isn't it reasonable to expect some unknown peaks to occur from time to time? 14:07
MR. STANOCH: Objection. 14:07
THE WITNESS: It is reasonable. But each time they occur, they need to be questioned. They can be a small thing. They can be a large thing. They can significantly affect the ability of the method to quantitate materials of interest that you are trying to test for. So when a peak occurs, it's -- it's important to question what -- what does this peak represent. 14:07
BY MS. LOCKARD: 14:07
Q. So in order to give rise to a question, does the peak need to reach a certain peak size, peak distribution, or width or shape in the substance? 14:07
A. No. It can be unexpected. "We haven't seen this before." 14:07
Certainly something that is baseline noise is one thing. But there are factors, there are measures within the chromatography for baseline noise. So that's not something of concern. 14:08

Page 179

But if you find something that appears or shouldn't be there, then a question should arise at that point. 14:08
Q. And when you say "ask questions" or "a question should arise," what specifically are you requiring a finished dose manufacturer like Teva to do in response to a discovery that there are unknown peaks in the supplier's raw data? 14:08
A. In their raw -- in the supplier's raw data? 14:08
Q. Well, I believe you told me that Teva should have been reviewing and comparing the supplier's raw data with their own; correct? 14:08
A. That is correct. But Teva would have to have their own raw data. As I understand it from the documents I reviewed, Teva didn't have their own raw data. 14:09
Q. Assuming Teva has raw data that exists, it includes unknown peaks, what is your expectation for what Teva would then be required to do in response? 14:09
MR. STANOCH: Objection. 14:09
But go ahead. 14:09
THE WITNESS: Hypothetically, because they don't have that chromatography, I would expect them to first investigate is this -- a contaminant from the 14:09

Page 180

sample preparation or from the glassware preparation. 14:09
In my experience, many times, the sudden appearance of an unknown peak or something we haven't seen before may be some extrinsic contaminant. 14:09
Glassware needs to be extremely clean when preparing samples, otherwise, it may carry over, and something will appear in the chromatography. 14:09
That would be the first investigation that would be -- that I would expect a manufacturer to -- to start with. 14:10
BY MS. LOCKARD: 14:10
Q. And is your response the same to the extent that a finished dose manufacturer sees that there are unknown peaks in the API manufacturer's data? 14:10
A. I would expect them to ask the supplier "What are these peaks? Did you have problems? Is this glass? This is something we haven't seen before." I would ask them to begin to query the supplier about the presence of unknown peaks. 14:10
MS. LOCKARD: Okay. Next exhibit. 14:11
THE REPORTER: 18. 14:11
MS. LOCKARD: 18. 14:11
(Deposition Exhibit 18 was marked for identification and is attached hereto.) 14:11

Page 181

BY MS. LOCKARD: 14:11
Q. All right. Are you familiar with this document as well? 14:11
A. Yeah. This appears to be the combination product Valsartan-HCTZ, USP. 14:11
Q. And this is for the tablets or the drug product? 14:11
A. The drug product. 14:11
Q. So if you look on Page 3 of this under "Acceptance Criteria," similarly here you see the acceptance? 14:11
A. I do. 14:11
Q. Okay. And, again, are these the compendial standards that you were referencing earlier in your report about ensuring compliance with compendial standards? 14:11
A. The USP standard, it can -- depending upon the geography, it can also be on the compendial standards, which exist. USP is not the only compendial standard. But, yes, that is what I am referring to. 14:12
Q. So is the -- is the ICH Q3A also a compendial standard? 14:12
A. No. I would be referencing the European Pharmacopoeia or the Japanese Pharmacopoeia. 14:12

Page 182

Depending upon what geographies' products are being sold, certain compendial requirements apply. 14:12
MS. LOCKARD: All right. Well, let's -- I'll make this an exhibit as well. 14:12
(Deposition Exhibit 19 was marked for identification and is attached hereto.) 14:12
BY MS. LOCKARD: 14:12
Q. Can you identify this document for me? 14:12
A. Yes. This is the impurity guidance ICH Q3A. 14:12
Q. And you are familiar with this document as well? 14:12
A. I am. 14:12
Q. Doesn't this include the reporting threshold for impurities? 14:12
A. It does. 14:12
Q. In ICH -- and ICH Q3B [verbatim]? 14:12
A. It does. 14:12
Q. Is there a reporting threshold for impurities in ICH 3- -- Q3B? 14:12
A. Is this -- this is Q3A? 14:13
Q. It is Q3A. Hold on a second. 14:13
We'll come back to that. 14:13
MS. LOCKARD: Okay. Let's mark Q3B as the next exhibit. 14:13

Page 183

(Deposition Exhibit 20 was marked for identification and is attached hereto.) 14:13
BY MS. LOCKARD: 14:13
Q. Are you familiar with this document? 14:13
A. I am. 14:13
Q. Okay. And what is this? 14:13
A. This is for drug products. This is impurities guidance for drug products Q3B (R2) [witness indicates documents]. 14:13
And this is for drug substances Q3A [witness indicates documents]. 14:13
Q. Okay. And is there a reporting threshold for impurities in ICH Q3B? 14:13
A. There are some reporting thresholds in Attachment 2. Yes. 14:14
Q. And the FDA follows this standard as well, doesn't it? 14:14
A. The FDA produce the guidance, and they don't test anything. So they are not following these standards, but they are -- they promulgated these standards. 14:14
Q. So FDA promulgated these standards; correct? 14:14
A. Yes. 14:14
Well, ICH did, but FDA accepts it. 14:14

Page 184

Q. So you don't mention the Q3A or Q3B standards in your report at all; correct? 14:14
A. No. My report doesn't -- doesn't criticize the fact that either the drug substance or the drug product met any compendial or recommended thresholds for impurities. 14:14
My report purely questions why Teva under Torrent did not question the presence of potential unknown peaks in chromatography that have nothing to do with the specifications. 14:14
Specifications are one evaluation criteria. The presence of something strange or something different in chromatography is also an evaluation criteria. I don't have any concerns that products that meet the thresholds or the specifications that were published. 14:15
Q. Did you review any of the impurity results, the impurity levels that were produced in the case related to ZHP's API? 14:15
A. As it relates to expected impurities or... 14:15
Q. The NDMA impurity that was found. Have you -- have you assessed the levels of NDMA that were found in the ZHP API? 14:15
A. I have seen documentation that demonstrates testing on methodology that was focused 14:15

Page 185

at looking at nitrosamines. 14:15
Q. And you are aware that even at the highest levels of impurities reported in any ZHP API anywhere in the world, the testing showed, according to these standards in the compendial specifications, that the impurities were below the reporting thresholds; correct? 14:16
MR. STANOCH: Objection. 14:16
THE WITNESS: I'll stipulate to that. Yes. I mean, my concern, again, isn't about the meeting of specifications. That's why I don't refer to any of these documents or the specific drug substance or product or drug product specifications because my concern is not about whether these products met specification. 14:16
My concern is whether or not firms were doing adequate monitoring of chromatography coming from the supplier. Purely if anything appeared that should not have been there or had not been there previously. 14:16
MS. LOCKARD: Okay. Let me show you -- we'll make this Exhibit 21. 14:16
(Deposition Exhibit 21 was marked for identification and is attached hereto.) 14:17
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Page 186

BY MS. LOCKARD: 14:17
Q. And this is the "FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings," dated August 30th, 2018, from Scott Gottlieb. 14:17
Are you familiar with this document? 14:17
A. I'm familiar with the document in that it exists. 14:17
Q. Have you read this or reviewed this? 14:17
A. Not in detail. 14:17
Q. And this was highlighted by one of the defense counsel on our team. So... 14:17
If you'll turn with me to Page 1 -- to 3, and starting at the bottom where it is highlighted where it says [as read]: 14:17
"Specifically, a combination of conditions, which include certain chemicals, processing conditions and production steps, could lead to formation of the NDMA impurity. We believe that these risks are introduced through a specific sequence of steps in the manufacturing process, where certain chemical reactions are needed to form the active ingredient. Before

Page 187

we undertook this analysis, neither regulators nor industry fully understood how NDMA could form during this process." 14:18
Do you agree with that statement? 14:18
MR. STANOCH: Objection to form. 14:18
THE WITNESS: I have no basis to agree or disagree with it. 14:18
BY MS. LOCKARD: 14:18
Q. Is it a reasonable conclusion to state that at the time of the discovery of the NDMA neither the regulatory agency nor the industry itself understood how NDMA could form in the drug? 14:18
MR. STANOCH: Objection to form. Misstates the document. 14:18
Go ahead. 14:19
THE WITNESS: I don't understand whether -- I would have to understand the chemistry that was associated with this. It's one thing to say that it's impossible or to know the chemistry here. 14:19
As I understand it from review of ZHP's own internal evaluation and investigation documentation that the chemistry was reasonably well-known and that this chemistry in the formation of the nitrosamines is a well-known reaction -- type of organic chemistry

Page 188

reaction. So this seems to be in conflict with that. 14:19
But, again, this is not my area of expertise; so I can't comment on this, on whether it's valid or not. 14:19
BY MS. LOCKARD: 14:19
Q. Well, in your practice as an industry consultant, you were not aware or had not considered the potential for the formation of nitrosamines in NDMA in the presence of drug substances, had you? 14:19
MR. STANOCH: Objection to form. 14:20
THE WITNESS: I am -- in my report I am not even looking at how NDMA was formed. My only concern and question is that something formed, something appeared in chromatography, and no one questioned it. 14:20
The -- the foregoing identification and then what chemistry led to that is a future state, and that's not my concern. 14:20
I was asked to opine on the GMP practices of Teva and Torrent. The GMP practice would be to question an unknown peak. What happens beyond that and the reasonableness of the chemistry is not part of my report, nor is it something I can comment on. 14:20
BY MS. LOCKARD: 14:20
Q. Okay. So I understand. 14:20
So your criticism is that the

Page 189

manufacturers did not question the unknown peak, period; right? 14:20
A. Correct. 14:21
MR. STANOCH: Objection to form. 14:21
BY MS. LOCKARD: 14:21
Q. You are not criticizing the manufacturers because they didn't then interpret the peak to be the presence of NDMA? 14:21
MR. STANOCH: Objection to form. 14:21
THE WITNESS: I'm not criticizing -- I'm criticizing them for not furthering an investigation that might lead to that identification. 14:21
BY MS. LOCKARD: 14:21
Q. But in terms of your background, experience, and education, you are not qualified to say that through the processes available at the time, the equipment available at the time, and the procedures available at the time, that a manufacturer could have or should have interpreted those peaks to be, in fact, nitrosamines? 14:21
MR. STANOCH: Objection to form. 14:21
THE WITNESS: I -- I would expect them to pursue an investigation that would lead them to that space. 14:21
Certainly, I understand the technology and

Page 190

what they would employ as they went along. 14:21
The perfect example is Novartis. They did 14:21
exactly what Teva and Torrent should have done. They 14:21
questioned the peak. The peak appeared in normal 14:22
compendial testing. They asked the question of the 14:22
supplier. The supplier failed to provide adequate or 14:22
reasonable responses in a reasonable time. And they 14:22
then, through investigation, decided to further 14:22
characterize those peaks themselves, which is exactly 14:22
what any prudent reasonable manufacturer should do. 14:22
BY MS. LOCKARD: 14:22
Q. But you are not testifying, then, in this 14:22
case that Teva had the ability, the equipment, the 14:22
validation -- validated procedures to be able to 14:22
interpret the peaks as ultimately being 14:22
nitrosamines? I mean, you are not connecting that 14:22
dot; correct? 14:22
MR. STANOCH: Objection to form. Objection. 14:22
Go ahead. 14:22
BY MS. LOCKARD: 14:22
Q. Go ahead. 14:22
A. I -- I do connect that dot. I have done 14:22
this work myself as a quality professional. In that 14:22
something is questioned. There is all kinds of 14:22
industry resources. I don't need to have those 14:23

Page 191

resources in house. It's available to me. 14:23
I can send this material to multiple 14:23
contract laboratories that could do an 14:23
investigation. 14:23
I am not trying to say what the specific 14:23
amount is or to validate this method. I'm just 14:23
trying to get information at this point. 14:23
So certainly they had access to all the 14:23
technology that would be needed in order to identify 14:23
these peaks. 14:23
BY MS. LOCKARD: 14:23
Q. What is the methodology that was needed to 14:23
identify the peaks? 14:23
A. There could be many different types of 14:23
technology that would be employed. All I can state 14:23
is that, again, we go back to Novartis. They choose 14:23
to use GC mass spec or GC-MS to do an 14:23
identification. 14:23
GC mass spec is a typical technology. 14:23
It's been around for decades. It's available in 14:23
almost every characterization lab. 14:23
So if Teva in their own laboratories did 14:23
not have GC mass spec, they could certainly send it 14:23
out for that type of evaluation. But there are 14:24
other methods of evaluation as well that they could 14:24

Page 192

use. 14:24
Again, the chemistry on how they might 14:24
want to approach that is for the scientists to 14:24
determine. 14:24
As the quality professional, I just want 14:24
an answer "What is this peak." 14:24
Q. Do you know whether Novartis used a 14:24
validated analytical test method to identify the 14:24
NDMA? 14:24
A. I -- I don't know if they used an I -- a 14:24
validated method. It would be unexpected that they 14:24
used a validated method to do an ID. 14:24
Q. On -- returning to the exhibit that is in 14:24
front of you, if you look at Page 5 of 7, the 14:24
highlighted sentence in the first paragraph says 14:25
[as read]: 14:25
"Because it was not anticipated that 14:25
NDMA would occur at these levels in the 14:25
manufacturing of the Valsartan API, 14:25
manufacturers would not have been 14:25
testing for it." 14:25
Do you see that? 14:25
A. I do. 14:25
Q. And that's a statement issued by FDA; 14:25
correct? 14:25

Page 193

A. It is. 14:25
Q. Do you disagree with that statement? 14:25
A. I don't disagree with this statement. 14:25
It was unexpected. It shouldn't have been 14:25
there. They wouldn't have designed testing to look 14:25
for it because it's not supposed to be there. 14:25
But when something strange appears, it's 14:25
incumbent upon them to identify what that is. 14:25
And, again, that is my only -- that's all 14:25
I have ever opined on in my report is that they 14:25
should have asked the question. They didn't ask a 14:25
question. 14:25
I am not saying that they should have 14:25
designed the testing up front to search for NDMA. 14:25
It's not expected to be there. They only need to 14:26
design testing for what they expect to be there. 14:26
But when a peak occurs that is unexpected, 14:26
even if it's below the threshold of reporting or 14:26
below the specification, a question should be asked. 14:26
Q. But don't you have to know what you are 14:26
looking for before you design a test to find it? 14:26
A. No. I can send it to a characterization 14:26
laboratory and say "Tell me what this is." I don't 14:26
need to know the amount of it. I just want to know 14:26
what it is. 14:26

Page 194

MS. LOCKARD: Here's the next exhibit, which is Number... 14:26
THE REPORTER: 22. 14:26
MS. LOCKARD: 22. 14:26
(Deposition Exhibit 22 was marked for identification and is attached hereto.) 14:26
BY MS. LOCKARD: 14:26
Q. This is the "FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues." 14:26
Immediate release was January 25th, 2019, authored by Scott Gottlieb. 14:26
A. Okay. 14:27
Q. Have you seen this document in your review? 14:27
A. No, I did not look at this document, that I am aware of. 14:27
Q. If you turn to Page 3 of 6, please, the highlighted portion at the bottom of the page reads [as read]: 14:27
"Tests are selected based on assessments of what impurities may develop as a result of the manufacturing process. In other words, 14:27

Page 195

it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for." 14:27
A. Correct. 14:27
Q. Do you see that? 14:27
A. I do. 14:27
Q. Do you agree with that? 14:27
A. Yes. Prospectively. If I'm going to prospectively design a method to look for an impurity, then I should have an expectation that impurity may exist in the product or from the manufacturing process could arise. 14:27
This is a statement about creating prospective testing. 14:28
If I find something that wasn't a part of my prospective evaluation, then it's incumbent upon me to ask a question "What is this? Did something change?" And then to characterize that because, potentially, I missed something in that prospective design. 14:28
Q. Before we undertook this analysis, neither regulators nor industry fully understood how NDMA or NDEA could form during this particular manufacturing 14:28

Page 196

process. 14:28
So this is new information to you? 14:28
A. No. I would expect that they would not have anticipated that these would -- prospectively, when they design methodology would have no expectation, nor do I opine in my report that they would have -- that I would have expectation that they would have designed upfront methodology that would be sent to FDA for approval to search for NDMA or NDEA. Neither of these impurities. They were unexpected. 14:28
Now, ZHP may have known about them, but didn't supply that in their technical packages to the customers or whatever it may be. I don't know that as well. 14:29
However, the statements that FDA is giving here is that should they have designed testing to look for NDMA. I agree they -- it wouldn't have been reasonable for them to do so. 14:29
But after finding unknown peaks, did you ask the question to ask what those peaks are. That's what I'm opining in my report. 14:29
Q. I understand. 14:29
A. Uh-huh. 14:29
Q. That -- that has come across, I think, 14:29

Page 197

fairly clearly. 14:29
On the next page of this, one challenge we face is that NDMA's properties make it hard to detect in standard laboratory testing the kind of testing results that are reviewed during a surveillance inspection. 14:29
You have no reason to quarrel with that? 14:29
A. I don't have any reason to quarrel with that. But having something -- if something is difficult, then it's difficult. If it's too difficult, you shouldn't be in this business. 14:30
Q. So your opinion now is that, because it's a difficult business, manufacturers should not be in it? 14:30
MR. STANOCH: Objection. Argumentative. 14:30
THE WITNESS: Okay. I -- I apologize for that. 14:30
MS. LOCKARD: Well, the answer, respectfully, was argumentative. 14:30
MR. STANOCH: Well, respectfully, you've raised that same objection for much less argumentative things I have said over the years. 14:30
So objection stands. Argumentative. 14:30
BY MS. LOCKARD: 14:30
Q. Okay. I think we can move those to the 14:30

Page 198

side. 14:30
Let me ask you this question: 14:30
Do you have an opinion about which 14:30
specific cGMP was violated by Teva? Not just the 14:30
cGMPs but by regulation number. 14:30
A. 21 CFR 211.84(d)(2). 14:30
Q. And -- okay. Are there any others or is 14:31
that the one that really encompasses the core of 14:31
your opinions? 14:31
A. I think that's the main core of my 14:31
opinion. Certainly there are other violations as it 14:31
relates to personnel training and various others, 14:31
potentially, that relates to Torrent, for the most 14:31
part, but this is the main focus. This particular 14:31
regulation is the main focus of my opinion in this 14:31
report. 14:31
Q. So for purposes of Teva because that -- I 14:31
need to know this as to what regulation we are being 14:31
accused of violating -- it's 211.84(d)(2)? 14:31
A. Correct. 14:31
Q. At the end of the report, there -- there's 14:32
the discussion about the timeliness of the recall 14:32
and removing the hold on the product, and there's 14:32
some commentary there about Mylan and the Mylan API. 14:32
I know that you said that, you know, this 14:32

Page 199

report isn't intended to really address the Mylan 14:32
API issues; right? 14:32
A. It's not. No. 14:32
Q. Okay. Is it your understanding that the 14:32
NDEA impurities in the Mylan product were processed 14:32
impurities generated by the same route of synthesis 14:32
in the ZHP? 14:32
MR. STANOCH: Objection to form. He's not 14:32
offering opinions on the Mylan API at this stage. 14:32
THE WITNESS: I'm not offering opinions on 14:32
Mylan; and, again, I didn't focus on that area. 14:32
My -- my main focus of including Mylan in 14:33
this is around Teva's failure to extend their 14:33
investigation to other suppliers of Valsartan, which 14:33
is an expectation of the GMP. 14:33
BY MS. LOCKARD: 14:33
Q. So you just don't know one way or the 14:33
other whether the Mylan NDEA issue was caused by the 14:33
same route of synthesis or something different? 14:33
MR. STANOCH: Same objection. 14:33
He is not opining on the Mylan API at this 14:33
stage. 14:33
THE WITNESS: I don't have any opinion on 14:33
that. 14:33
///

Page 200

BY MS. LOCKARD: 14:34
Q. So you are not offering any opinions at 14:34
this stage as to whether Teva should have released a 14:34
hold on the Mylan product; right? 14:34
A. I am offering opinion that they should not 14:34
have released a hold on Mylan product because they 14:34
hadn't received appropriate documentation from all 14:34
of their suppliers that would give them a high 14:34
enough degree of assurance that this problem that 14:34
ZHP reported did not exist amongst those suppliers. 14:34
The GMP requires an extension or a -- to 14:34
throw a larger net to the investigation to all 14:34
suppliers who potentially produce -- who produce 14:34
Valsartan for you. That is a standard-industry 14:34
practice. 14:34
There is a problem identified, ZHP's. 14:34
Valsartan was identified to have a problem. 14:34
Before I released any other Valsartan that 14:34
I may receive from other suppliers, I need to 14:35
solicit -- again, ask questions and solicit 14:35
appropriate objective evidence that this problem 14:35
doesn't exist within their drug substances. 14:35
And it appeared to me from the 14:35
documentation and from the emails that I reviewed 14:35
that Teva did not have appropriate documentation to 14:35

Page 201

release Mylan's material for further processing. 14:35
Q. Did you review documentation of the 14:35
communications between Mylan and ZHP that included 14:35
questions that ZHP had asked -- excuse me -- 14:35
included questions that Teva had asked and that 14:35
Mylan responded to? 14:35
A. I reference them in my report. This is 14:35
the documentation that I looked at. 14:35
Q. And the documentation reviewed indicated 14:35
that Mylan confirmed it was a different route of 14:35
synthesis and would not contain NDMA. 14:35
Did you see that in the document? 14:35
A. They stated that, but they -- there's no 14:35
objective evidence. A statement -- a statement of, 14:36
you know, a condition by a supplier is not 14:36
sufficient. Again, I trust but verify. 14:36
And I have an email listed here where the 14:36
person responsible for this is stating "We have not 14:36
received objective evidence that supports this 14:36
statement," but a decision was made to release 14:36
products anyway. 14:36
Q. So you are critical of Teva's acceptance 14:36
of a statement that ultimately turned out to be 14:36
accurate? 14:36
MR. STANOCH: Objection to form. 14:36

Page 202

THE WITNESS: I am critical of it because 14:36
there wasn't objective evidence provided with that 14:36
statement. They jumped the gun. 14:36
BY MS. LOCKARD: 14:36
Q. Do you have an understanding as to the 14:36
reason for releasing the hold on the Mylan product 14:36
being a potential concern for shortage in the 14:36
market? 14:36
A. Yes. A potential concern for shortage, in 14:36
my view, it's probably more a potential concern for 14:37
a loss of revenue. 14:37
Q. Well, that's your speculation; correct? 14:37
MR. STANOCH: Objection to form. 14:37
THE WITNESS: It's based on my experience 14:37
sitting in board rooms making this decision or similar 14:37
decisions. This appears to be a decision where 14:37
marketing was driving what quality decisions need to 14:37
be made. 14:37
Again, if I'm the quality leader here, I 14:37
want objective evidence that demonstrates the other 14:37
suppliers -- statements that they have made before I 14:37
place them in the investigation are verified. I may 14:37
even want to do a for-cause audit or maybe even visit 14:37
Mylan before I start releasing Mylan's products. That 14:37
would be what I would have done. 14:37

Page 203

BY MS. LOCKARD: 14:37
Q. Did you see any documentation about Teva's 14:37
request for an audit from Mylan? 14:37
A. Not that I recall off the top of my head. 14:37
No. 14:37
Q. Ultimately, though, whatever Teva did with 14:38
respect to the Mylan product played no role in 14:38
causing any damages or injury to consumers of the 14:38
Valsartan provided with ZHP API; right? 14:38
MR. STANOCH: Objection to form. 14:38
THE WITNESS: I have no statement on that. 14:38
I have no opinion on that. My concern -- again, the 14:38
reason I wrote this report and what I was requested to 14:38
do was to ask whether they follow -- their GMP 14:38
behaviors were compliant or consistent with industry 14:38
standard and regulation. 14:38
I haven't made any statements other than 14:38
that within my report. 14:38
BY MS. LOCKARD: 14:38
Q. There's also criticism in your report 14:38
about Teva's alleged delay in reporting the 14:38
impurities to the FDA. 14:38
But your own report states that Teva was 14:38
informed only of a potential genotoxic impurity by 14:38
ZHP on June 20th, not the presence of nitrosamines; 14:39

Page 204

correct? 14:39
A. Correct. 14:39
Q. So you understand that -- that ZHP had not 14:39
yet reported the presence of a genotoxic impurity 14:39
being nitrosamines as of the 20th? 14:39
A. That's what I have stated in the report. 14:39
Q. Is it your position that -- that, 14:39
nonetheless, Teva should have then reported to FDA 14:39
about an unknown genotoxic impurity that was being 14:39
investigated by ZHP? 14:39
A. It is. There is a -- a consistent 14:39
disagreement between FDA and industry as it relates 14:39
to what is called a "Field Alert Report" or a 14:39
"Notification." 14:39
FDA's view is that you -- the clock of 14:39
three days starts when you are notified of a 14:39
potential issue. Industry says that that clock 14:39
starts when you confirm the presence of 14:40
nitrosamines, let's say, in a field alert. 14:40
This is a -- a battle between the 14:40
regulator and industry. It's a consistent battle. 14:40
To follow what FDA believes is the appropriate 14:40
approach is when you are notified. 14:40
Q. So you would agree then, though, that 14:40
Teva's approach in reporting was at least consistent 14:40

Page 205

with industry standard? 14:40
MR. STANOCH: Objection to form. 14:40
THE WITNESS: It appears that they had 14:40
different views on when they should notify FDA. 14:40
Again, I wasn't present during the decision 14:40
processes for these. I can only state that, in my 14:40
experience, many firms tend to delay in notifying the 14:40
regulator about issues that they encounter and that 14:40
Teva appeared to not come in full compliance and 14:41
alignment with their three-day frequency for field 14:41
alert reporting. 14:41
BY MS. LOCKARD: 14:41
Q. Your testimony just moments ago was that 14:41
industry standard says that the clock starts when 14:41
you confirm the presence of nitrosamines. 14:41
So the industry standard is that the clock 14:41
starts when you confirm the presence of 14:41
nitrosamines; correct? 14:41
A. It's not industry standard. It's what 14:41
industry believes. 14:41
An industry standard is an accepted 14:41
practice that industry follows. The accepted 14:41
practice around field alerts is it's from 14:41
notification. 14:41
Industry believes that they need to 14:41

Page 206

confirm something before that. That is not an industry standard. That doesn't mean that it applies or becomes part of current manufacturing practice. Because an industry standard becomes part of good manufacturing practice. It's the "C" in GMP. 14:41 14:41 14:41 14:42 14:42 14:42

Q. Current Good Manufacturing Practice is based on federal regulations; correct? 14:42 14:42

A. It is based on regulation. The regulations are from the 1970s. So everything the industry has done in innovation and enhancement also becomes part of the current good manufacturing practice. 14:42 14:42 14:42 14:42 14:42

Q. Isn't industry standard what is reasonably done by prudent manufacturers in the industry? 14:42 14:42

A. It is. I agree with that statement to some extent. 14:42 14:42

Q. So if industry standard is what is reasonably done by prudent manufacturers and prudent manufacturers routinely say the clock starts when you confirm the presence of nitrosamines, then didn't Teva follow the industry standard? 14:42 14:42 14:42 14:42 14:42 14:42

MR. STANOCH: Objection to form. 14:43

THE WITNESS: You are assuming that I would consider Teva in this particular case to be prudent. 14:43 14:43

Page 207

I don't. 14:43

I work with many firms who have a belief that even proceduralize that they will need to confirm before they report. This is not, to me, prudent in any way. 14:43 14:43 14:43 14:43

BY MS. LOCKARD: 14:43

Q. No. No. My question does not imply that -- that you think Teva's prudent. 14:43 14:43

My question to you is that, if prudent manufacturers in the industry follow a rule that says the clock starts ticking when you confirm the presence of nitrosamines and that's what Teva did, then Teva complied with the industry standard followed by prudent manufacturers? 14:43 14:43 14:43 14:43 14:43 14:43 14:43 14:43

MR. STANOCH: Objection to form. 14:43

THE WITNESS: I am -- I am saying that that approach is not prudent. It doesn't align with what the regulator recommends or what the -- the regulator actually requires. 14:43 14:43 14:43 14:43 14:43

In many cases -- and you can find observations from FDA that deal with this specific issue -- that a firm is cited for taking that stance. 14:43 14:44 14:44

So that clearly is not prudent when FDA cites you in an observation for taking that stance. That's not prudent in any way, whether it's Teva or 14:44 14:44 14:44 14:44

Page 208

any other manufacturer. 14:44

MS. LOCKARD: I am getting very close to being done. I have a set of exhibits that we need to go through -- that I need to get from the other room to go through in the deposition. 14:44 14:44 14:44 14:44

I can either take a break, get those, and do that. 14:44 14:44

We can let counsel from Torrent ask questions. I do want to give her an opportunity to ask because I have taken time. 14:44 14:44 14:45

But I would like to reserve a little time after that to be able to ask the remainder of my questions once I get my exhibits. 14:45 14:45 14:45 14:45

MR. STANOCH: Well, let's go off the record either way. 14:45 14:45

MS. LOCKARD: Off the record. 14:45

THE VIDEOGRAPHER: Okay. Going off record at 2:45 p.m. 14:45 14:45

(Brief recess.) 15:17

THE VIDEOGRAPHER: And we are back on the record at 3:18 p.m. Start of Media Number 6. 15:17 15:17

BY MS. LOCKARD: 15:18

Q. Okay. Mr. Russ, are you good? 15:18

A. Yes. 15:18

Q. All right. Turning to your report, I want to focus your attention now on Page 15 -- 15:18 15:18

Page 209

THE VIDEOGRAPHER: [Videographer gestures]. 15:18

BY MS. LOCKARD: 15:18

Q. Mr. Russ, turning to your report, I want to focus your attention now on Page 15, Paragraph 85 and 86. 15:18 15:18 15:18

A. Yes. 15:18

Q. This is where you are offering opinions about the change control process once ZHP initiated their change in November of 2011. 15:18 15:18 15:18

Are you with me? 15:18

A. I am. Yes. 15:18

Q. Okay. So as you state in Paragraph 86, [as read]: 15:18 15:18

"It appears Actavis opened a change control to process this change. ZHP sent an additional change request notification to Actavis dated October 18th, 2012, to add a 3rd dedicated workshop. It appears Actavis opened change control to process this change." 15:18 15:19 15:19 15:19 15:19 15:19 15:19 15:19

Now, the document that you reference is Bates -50662? 15:19 15:19

A. Correct. 15:19

Page 210

MS. LOCKARD: Let's make that Exhibit 23. 15:19
(Deposition Exhibit 23 was marked for identification and is attached hereto.) 15:19
BY MS. LOCKARD: 15:19
Q. And in your report, you focus on three action items or action descriptions that you found to be relevant to put in your report. 15:19
A. Yes. 15:19
Q. And the first was, as you discuss in Paragraph 87, at the bottom [as read]: 15:19
"One of the actions from the change control stated, to evaluate whether this change can affect the current validated method for testing the API, especially as regards the residual solvents for the new Valsartan tin-free with zinc chloride process." 15:20
Correct? 15:20
A. Correct. 15:20
Q. All right. And so if you'll look at Exhibit 23, that is reflected -- 15:20
A. Yeah. Let's find it. 15:20
Q. It's on Page 8. 15:20
A. Okay. Thank you. 15:20
Yes. 15:20

Page 211

Q. And the "Action Status" there is indicated "Fully complete"; right? 15:20
A. Yes. 15:20
MS. LOCKARD: And let's mark this as Exhibit 24. This is the risk assessment for the use of -- strike that. 15:20
Let's mark this as 24. And this is Bates -20264 from Teva's set. 15:21
(Deposition Exhibit 24 was marked for identification and is attached hereto.) 15:21
BY MS. LOCKARD: 15:21
Q. And if you look at the first page of the document, it says "Arrow Pharm Validation Department." And the title of the document is "Analytical Method Validation Report for Valsartan Raw Material-Residual Solvents." 15:21
So isn't it correct that that action description was completed as is reflected in Exhibit 24 that I have just provided to you? 15:21
A. Yes. 15:21
Q. Okay. Your only criticism of this completion of this action item is that you don't find evidence of testing as part of the validation process? 15:21
A. No. My -- my concern here is that they 15:21

Page 212

didn't -- in the evaluation they have described it [as read]: 15:22
"No further validation was required. The specification parameters are already covered by previous validations performed for Valsartan." 15:22
The -- this exhibit that you have shown me, which is unmarked, is -- 15:22
Q. 24. 15:22
A. Okay. This is 24. It's dated in 2010. 15:22
So they said that this particular method was adequate for residual solvent testing for this changed product. 15:22
But they never performed any testing of new product with this method. They're -- I would expect that they -- here would also say, "We ran a sample according to this method and reviewed the chromatography and it was acceptable." 15:22
They just said, "We already have a validation. It's good." 15:22
That's my concern. It's not -- not that they didn't -- they didn't run this method with the new material as part of this change control. 15:23
Q. Okay. So how -- describe for me what you think the testing is that they actually should have 15:23

Page 213

completed in order to perform this action description? 15:23
Is there a specific -- 15:23
A. Run a sample using this with the new method and say, "The chromatography looks the same as it did previously." The system suitability, all the retention times for peaks are appropriate. 15:23
There's no report that the validation is adequate other than "No further validation is required." 15:23
Based on what? Specification parameters and limits are already covered. Okay. It has the same specs. But why is it okay for this new process? This statement has no basis. 15:24
There is no objective evidence that demonstrates to me this method is adequate for this purpose. It may be. But there is no data that demonstrates that it's attached to the change control. 15:24
Q. So you would be looking for chromatology results that were the same for the old process API and the new process? 15:24
A. Well, that is comparative testing. That's ideal with -- later down the line when they -- we'll get to that, I assume. 15:24

Page 214

Here I am just expecting that they ran a sample using this method and did a comparison chromatography. 15:24

That would be the right evaluation to say that this method is still adequate for the new process. They didn't do that here. They just said "it's adequate for the new process" without any objective evidence to support that. 15:24

Q. The second action item that you point out is on Page 8 of 12 and the action description is [as read]: 15:24

"Fully test first five batches of upscale batch size" -- 15:25

A. Yes. 15:25

Q. [As read]: 15:25

-- "of Valsartan." 15:25

Now, as you note in your report, however, the "Action Status" here says "Fully complete"; correct? 15:25

A. Yes. 15:25

Q. So from this, this documentation leads one to the conclusion that full -- that the five batches were tested as indicated here; correct? 15:25

A. No. Because the -- the action says that they are going to plan it for testing, but there 15:25

Page 215

is -- they never complete the testing. They close the action by planning the testing. 15:25

Q. But the action itself is to fully test, and the action status was fully complete? 15:25

A. Well, the action status is, but the -- 15:25

Q. That's what it says here. 15:25

A. -- statement for that action is that they just planned the testing, not that they completed the testing. 15:25

Q. Okay. So you don't find it credible evidence to say that the action -- 15:26

A. I only said it's unclear -- 15:26

MR. STANOCH: Well -- 15:26

THE WITNESS: -- if this testing ever took place. 15:26

BY MS. LOCKARD: 15:26

Q. Okay. 15:26

A. Because the action doesn't say "Here is the notebook reference for the testing of the five batches." That's what I would expect. Tell me where the testing is or give me the testing as an attachment to the change control. 15:26

Q. So your criticism is essentially in the way they documented this? 15:26

A. No. They didn't do the testing. 15:26

Page 216

Q. You don't know that they didn't do the testing. 15:26

MR. STANOCH: Objection. 15:26

THE WITNESS: They -- I -- it wasn't produced as part of the change control. It should have been. 15:26

BY MS. LOCKARD: 15:26

Q. Okay. 15:26

A. It's objective evidence that supports the closure of this change control. 15:26

Q. Okay. So Mr. Russ doesn't believe when it says "Fully complete" that that indicates the testing was fully done? 15:26

MR. STANOCH: Objection to form. 15:26

THE WITNESS: Can I read what it says? It says [as read]: 15:26

"The 'Record Sheet For Uncertified Suppliers' was created for items" -- something and something -- "to test the five batches manufactured in accordance with..." I guess that's the specification. 15:26

Again, they closed it, and the comment is "We plan to do this testing." They closed it with that. 15:27

Page 217

BY MS. LOCKARD: 15:27

Q. The comment indicates they initiated the testing process. The "Action Status" indicates it was "Fully completed." 15:27

MR. STANOCH: Objection. 15:27

BY MS. LOCKARD: 15:27

Q. You may disagree with the interpretation, but that's what it says there; correct? 15:27

MR. STANOCH: Objection. 15:27

THE WITNESS: It doesn't say that. 15:27

[As read]: 15:27

"The 'Record Sheet For Uncertified Suppliers' was created..." 15:27

That means they did planning. They planned the test, but -- and they closed it on a planned test. Hoping that it would occur. 15:27

There's not a comment stated here that "We tested these five batches, and they met all specifications. And chromatography was reviewed, and no anomalies were found." 15:27

That's what should be in the "Comment" section that demonstrates -- if you are not going to provide the data, that demonstrates to me that this testing was completed, and the testing wasn't produced to me. 15:28

Page 218

BY MS. LOCKARD: 15:28
Q. So you would be satisfied if you saw 15:28
chromatography results showing that there were 15:28
batches tested both before and after? 15:28
A. At least -- 15:28
MR. STANOCH: Objection to form. 15:28
THE WITNESS: -- tell me what batches were 15:28
done so I can go look at the data. 15:28
BY MS. LOCKARD: 15:28
Q. Okay. 15:28
A. And what you compared them with. 15:28
Q. Okay. 15:28
A. That's the purpose of the five batch 15:28
testing based on the risk assessment is to do that 15:28
comparative testing that I have described 15:28
previously. They planned it and closed the change 15:28
control in the planning. 15:28
Q. Right. 15:28
You haven't seen the evidence of the 15:28
comparative testing? 15:28
A. But I also want to state that -- 15:28
Q. Was that -- 15:28
A. -- closing a change control action with a 15:28
plan doesn't mean GMP requirements. If you say 15:28
"Test five batches," then to close this action, you 15:28

Page 219

must show the testing of those five batches to meet 15:28
GMP. 15:28
Q. Right. 15:29
So you are looking for documentation that 15:29
they tested five batches after -- after the change 15:29
was made, and that's compared with the batches 15:29
tested previously; right? 15:29
MR. STANOCH: Objection to form. 15:29
THE WITNESS: Correct. 15:29
THE REPORTER: Repeat your answer. 15:29
THE WITNESS: I'm sorry. 15:29
Correct. 15:29
BY MS. LOCKARD: 15:29
Q. All right. So the third item, action item 15:29
that you reference in your report is actually on 15:29
Page 7 of the change control report, and it was to 15:29
[as read]: 15:29
"Perform risk assessment whether the 15:29
new material from the new CEP and 3rd 15:29
dedicated workshop (upscaled batch 15:29
size) can have any impact on the 15:29
process validation of Valsartan 15:29
finished product." 15:29
Now, you reference in your report as well 15:29
that Teva did actually do a risk assessment; 15:29

Page 220

correct? 15:29
A. They did. 15:29
MS. LOCKARD: And this is -- we'll mark as 15:29
Exhibit 26. 15:29
(Deposition Exhibit 26 was marked for 15:29
identification and is attached hereto.) 15:29
BY MS. LOCKARD: 15:29
Q. And this is the risk assessment that Teva 15:29
did that you are referencing; correct? 15:30
A. Yes. 15:30
Q. And that item as well was marked as "Fully 15:30
complete"? 15:30
A. And I agree with that. 15:30
Q. All right. We can put those aside for the 15:30
moment. 15:30
MS. LOCKARD: All right. Let's get 15:30
Exhibit 26 up. 15:30
Let's go with 27. 15:30
(Deposition Exhibit 27 was marked for 15:30
identification and is attached hereto.) 15:30
BY MS. LOCKARD: 15:30
Q. Okay. You have stated, I think, multiple 15:30
times today you have not seen any documentation that 15:30
you reviewed that demonstrated routine 15:31
chromatography testing [verbatim] of the incoming 15:31

Page 221

API was done before and after the change control; 15:31
correct? 15:31
A. "Comparative testing." 15:31
Q. Comparative testing. 15:31
So we'll give you Exhibit 27. 15:31
This -- if you can identify for me what 15:31
this document appears to be. 15:31
A. It's an "Annual Product Review." 15:31
Q. Okay. And you testified earlier you have 15:31
not reviewed this; correct? 15:31
A. Again, I reviewed the source documents 15:31
that create -- that are used to create this 15:31
document. The primary records. 15:31
Q. This is the annual product report for the 15:31
Valsartan Hydrochlorothiazide combo product covering 15:31
2014 -- January 2014 through December '14; correct? 15:31
A. It is. 15:31
Q. All right. And if you turn to the Page 2 15:32
of the document, which is the "Table of Contents," 15:32
on the second page, first section is the "Product 15:32
Starting Materials Review." 15:32
A. Okay. 15:32
Q. And that's -- that means API; correct? 15:32
A. It does. And excipients. 15:32
Q. And if you look at the next page there, 15:32

Page 222

the chart, both the Valsartan and the Hydrochlorothiazide product are identified as being from ZHP. 15:32
A. Okay. 15:32
Q. And there's an API code associated there, the Valsartan API code -- there are two API codes for the Valsartan. 15:32
Do you see that? 15:32
A. Yes. 15:32
Q. Okay. And that is because, if you look down at the paragraph that starts [as read]: 15:32
"Eighty one batches...were supplied...." 15:32
It indicates that there was a new API code that was -- that was assigned after the change was made; right? 15:32
A. Correct. 15:33
Q. Okay. So this Annual Product Review itself covers product manufactured under both the old and the new API process, then; right? 15:33
MR. STANOCH: Objection. 15:33
Go ahead, if you can. 15:33
THE WITNESS: It -- it just states that they in manufacture of the finished product used two different codes, one that is prior to a change, and 15:33

Page 223

one that is after one. That's all. 15:33
BY MS. LOCKARD: 15:33
Q. Okay. And the product code was changed in order to reflect in Teva's documents which -- testing which references and so forth to the API related to the prior process versus the new process; right? That was the point of changing the API code. 15:33
A. It appears so. Yes. 15:34
For traceability purposes. 15:34
Q. All right. If you look at Page 5, next to the last paragraph, it says [as read]: 15:34
"No events were issued for the APIs during the review period. 15:34
"API batches were tested as per the current test methods and specifications and were released accordingly. All API test results were well within the control specification limits and are tabulated." 15:34
A. Correct. 15:34
Q. Then it says [as read]: 15:34
"(Refer to Attachment 1)." 15:34
A. Right. 15:34
Q. Now, it appears that your testimony has been that, whatever testing they are referring to on 15:34

Page 224

this page, your assumption is that it relates to testing that was done by ZHP and included in the CO- -- CofA? 15:34
MR. STANOCH: Objection to form. 15:35
BY MS. LOCKARD: 15:35
Q. Is that right? 15:35
MR. STANOCH: Same objection. 15:35
THE WITNESS: Yes. The data was transcribed into their system from the CofA. 15:35
BY MS. LOCKARD: 15:35
Q. That Teva transcribed the data provided by ZHP in their certificate of analysis into Teva's own system? 15:35
A. Yes. 15:35
Q. All right. So if you turn to Attachment 1, which is -- 15:35
A. Appendix 1. 15:35
Q. Excuse me. Appendix 1. It's where the Table 1 indicates "API Parameter Trending" at the top. 15:35
A. I have -- I have Appendix -- is it attachment or appendix or... 15:35
Q. Actually, it's Attachment 1. 15:35
A. Let me search. 15:36
MR. HARKINS: It's the first one on there. 15:36

Page 225

MS. LOCKARD: Table 1 or -- Attachment 1. I found it. 15:36
BY MS. LOCKARD: 15:36
Q. And there up at the top there is the code for VLS001 -- 15:36
A. Yes. 15:36
Q. -- which from the prior section means this is dated for API manufactured using the old process. 15:36
A. Right. 15:36
Q. Can we agree? 15:36
A. Yes. 15:36
Q. Okay. What -- what information is included on this table that you can tell? 15:36
A. "Batch Number," "Water" content, "Assay." 15:36
Q. Are these test results? 15:36
A. These are tests results that were transcribed from the certificate of analysis from ZHP. This is just a reiteration of what was sent to them from ZHP. 15:36
Q. Okay. Did you ever compare what is on this table with the actual certificates of analysis to see how they -- how they do, in fact, compare? 15:36
A. No. 15:37
Q. This table -- this includes -- this reflects chromatography results; right? 15:37

Page 226

A. This are -- are values from chromatography results. These are not chromatography results. So the chromatography is a graphic -- 15:37
Q. Graph. 15:37
A. -- format. Right? 15:37
Q. So there would be a graph that went along with this. But these figures indicate that chromatography was performed; right? 15:37
A. It appears from ZHP. And chromatography doesn't come with a certificate of analysis. 15:37
Again, they would have the opportunity at an audit to review Batch 246023 and verify these results. 15:37
Q. All right. My -- just my question is that this test results that are reflected in this table, these would have come from chromatography testing; right? 15:37
A. From ZHP. 15:37
Q. These test results would have come from some chromatography testing? 15:37
A. Not "Water." "Assay" potentially would have. "Impurity C" would have. The "Individual Impurities" would have. It depends on the method. 15:38
But, yes, they are results from analytical testing, which would include chromatographic testing 15:38

Page 227

that was performed at ZHP. 15:38
Q. If you look at the Batch Number, if you focus on, just to pick one -- 15:38
A. Uh-huh. 15:38
Q. -- the -- near the bottom, Batch 287859. 15:38
Do you see that? 15:38
A. 287879. Yes. 15:38
MR. HARKINS: Is it "59" or "79"? 15:38
MS. LOCKARD: I guess I need my reading glasses. 15:38
287859. 15:38
THE WITNESS: Oh. I'm sorry. The second to the last. Yes. 15:38
BY MS. LOCKARD: 15:38
Q. The second to the last. Okay. So there is a test for appearance -- 15:38
A. "Water," "Assay." 15:39
MR. STANOCH: Sorry. She can ask. 15:39
THE WITNESS: Okay. Sorry. 15:39
BY MS. LOCKARD: 15:39
Q. Hold on a second. Let me pull it up here. 15:39
MS. LOCKARD: All right. Let's -- let's do this. Let's get -- hold on to that one. Let's get the next document marked. 15:39
The next exhibit, which will be 28. 15:39

Page 228

(Deposition Exhibit 28 was marked for identification and is attached hereto.) 15:39
BY MS. LOCKARD: 15:39
Q. All right. And on this Arrow lot number first page -- first of all, what is -- what is this document that I have just handed you, Exhibit 28? 15:39
A. This is an internal certificate analysis for Valsartan, Code 287- -- or this is that lot that you have described, 287859. 15:40
Q. Okay. So it's the same lot number as the line item we were just looking at; correct? 15:40
A. It is. 15:40
Q. All right. So then turning to the third page, and it shows here there's a test for "Appearance"? 15:40
A. Uh-huh. 15:40
Q. "Identification." And it's all -- there are handwritten responses here; correct? 15:40
A. There are. 15:40
Q. Okay. And there is an identification test and the results of that test are performed by Arrow. They are shown there. 15:40
And then you if you turn the page, there is a test for "Absorbance," "Solubility," "Water," and a test for "Sulfated Ash/Residue." 15:40

Page 229

Do you see those? 15:41
A. I do. Yes. 15:41
Q. And then on the next page there is an "Assay" test that includes two parts, one for the EU, one for the U.S.; correct? 15:41
A. Correct. 15:41
Q. And that shows a result of 99.67 reported by Arrow for this -- for the U.S. test; right? 15:41
A. Correct. 15:41
Q. And there is a "Related Substance -- Substances" test which was done by HPLC, which is chromatography; right? 15:41
A. Yes. Yes. Yes. 15:41
Q. An "Enantiomeric Purity" test? 15:41
A. Uh-huh. 15:41
Q. Number 11, the "Related Substances - Test." 15:41
12, "Related Substances - Test" again. 15:41
Number 13, "Residual Solvents" test. 15:42
Finally, Number 14 is a "Particle Size" test with the results reported by Arrow in handwriting; correct? 15:42
A. Yes. 15:42
Q. And so you agree these reflect tests performed by Arrow in the incoming batch of API? 15:42

Page 230

A. I don't agree that that's the case. It's common for a manufacturer to transcribe various results to their own certificate of analysis internal for approval from the certificate analysis received from the supplier under a reduced testing program. 15:42
Q. On Page 8 you can see that the date of manufacturer is listed as August 2, 2014; right? 15:42
A. I -- I am sorry. On Page 8 of 9? 15:42
Q. Yep. There is a date of manufacture. It's handwritten. It's very light. "2 August 2014." 15:42
Do you see that? 15:43
A. [Witness reviews document]. 15:43
Oh. Yes. Okay. 15:43
Q. And turning past Page 9 of Arrow's testing results, there is a certificate of analysis from ZHP. And that ZHP Batch is listed as C5069-14-023M; correct? 15:43
A. Correct. 15:43
Q. And if you look at that, that's the first page -- I mean, that's the same as the batch number listed on the first page of Arrow's certificate of analysis testing. 15:43
A. Okay. 15:43

Page 231

Q. Where under ZHP, it's 650969-14-023M. 15:43
A. Uh-huh. 15:43
Q. Do you see that? 15:43
A. I do. 15:43
Q. And it's the same manufacture date for both of August 2, 2014. 15:43
A. Okay. 15:44
Q. On the certificate -- on the certificate with test, it shows a number of tests here. The first page -- 15:44
MR. HARKINS: You are on the second page? 15:44
MS. LOCKARD: Oh. 15:44
BY MS. LOCKARD: 15:44
Q. Yeah. The first page has tests for EU, and the second shows the tests for the USP product. 15:44
A. Okay. 15:44
Q. So looking at the USP product to focus you there. 15:44
Now, turning back to the "Annual Product Review" table, second from the bottom you see -- 15:44
A. Right. 15:45
Q. -- 287859. 15:45
The first column is for "Water"; right? 15:45
A. It is. 15:45
Q. And it says ".70"; right? 15:45

Page 232

Do you see that? 15:45
A. Yes. 15:45
Q. What value did ZHP report on its certificate of analysis for water? 15:45
A. .6 -- or am I on the right certificate? 15:45
Q. Yes. 15:45
A. Okay. 15:45
Q. And those are not the same? 15:45
A. No. 15:45
Q. We agree. 15:45
A. They -- they don't appear to be the same. No. 15:45
Again, there is one significant figure here, and there is two significant figures here. 15:45
.6 is .6. .64 is .6. It's about -- it's something called "significant figures." So I round this. I drop the "4" and it's .6. 15:45
Q. Okay. So on the -- if you follow along on the "Assay" test on the chart, it's "99.42." Yet on the ZHP certificate what do we have? 15:46
A. It appears to be 99.5. 15:46
Q. Okay. And those are not the same either; right? 15:46
A. Assay for U.S. -- it doesn't appear to be the same. No. 15:46

Page 233

Q. Looking at the "Related Substances" test on the right-hand side of the page, there is a column for "USP Valsartan Related Compound B" and the figure on the chart is point -- excuse me -- is "0.016." 15:46
Do you see that? 15:47
A. Yes. 15:47
Q. On ZHP's certificate of analysis for Compound B, what did they report? 15:47
A. Oh. They reported below the limit of quantitation. 15:47
Q. So no number at all; right? 15:47
A. Right. 15:47
Q. But Arrow's testing chart did report a finding for that test; right? 15:47
A. It does. 15:47
Q. In the second-to-last column on the chart, "Individual Impurities," Arrow reported it as .31 [verbatim]. 15:47
Do you see that? 15:48
A. Yes. 15:48
Q. And on the certificate of analysis for ZHP, for Individual Impurities, it's reported as .03; correct? 15:48
A. I think it's .05. 15:48

Page 234

MR. STANOCH: Uh-huh. 15:48
BY MS. LOCKARD: 15:48
Q. .05. Correct. 15:48
A. Uh-huh. 15:48
Q. In ZHP's certificate of analysis, they 15:48
reported to the hundredth decimal place. Whereas in 15:48
Arrow's chart, they reported to the thousandths 15:49
decimal place. 15:49
A. Okay. 15:49
MR. STANOCH: Objection. Misstates the 15:49
document. I see thousandths place on the ZHP one. 15:49
BY MS. LOCKARD: 15:49
Q. I could go through these, you know, in 15:49
individual detail, but the point I'm getting at is 15:49
that these numbers that were reported in Arrow's 15:49
testing and in the certificate of analysis, which 15:49
you say Arrow copied, are not the same numbers? 15:49
A. They are not. 15:49
Q. Does that then lead you to the conclusion 15:49
that perhaps Arrow did its own testing? 15:49
A. Perhaps. 15:49
Q. If the evidence shows that Arrow did its 15:49
own testing, does that remove your criticism that 15:49
Teva failed to comply with cGMP and industry 15:50
standards in not doing its own independent testing 15:50

Page 235

related with the process change? 15:50
A. I have already stated that it's acceptable 15:50
to be reduced testing or do your own testing. I 15:50
don't have any concern with that. 15:50
My concern is did they review the 15:50
chromatography for change for unknown peaks. If 15:50
these results were produced by Arrow, then they were 15:50
produced by Arrow. I don't have an issue with that. 15:50
I didn't opine that there was a concern 15:50
with the regulatory requirement to do testing on 15:50
drug substances or not based on reduced testing. 15:50
Did you evaluate the chromatography. 15:50
So in this case if they did their own 15:50
testing, did you review the chromatography? 15:50
When you went and did an audit then, did 15:50
you take chromatography from this period, you know, 15:50
a statistically significant number of batches, 15:51
look -- take your chromatography with you to China 15:51
and review it against their chromatography? Raw 15:51
data against raw data because that is what you are 15:51
supposed to do. 15:51
My issue is not that they did testing or 15:51
not. It appeared to me because I wasn't -- I didn't 15:51
see data testing for batches, that they didn't do 15:51
testing. My concern isn't that they didn't do 15:51

Page 236

testing. You are allowed to not do testing. 15:51
Q. Your criticisms all day, sir, 15:51
respectfully, have been that Teva did not do its own 15:51
testing and referred and -- and copied the results 15:51
from the ZHP certificate of analysis. 15:51
MR. STANOCH: Objection. 15:51
BY MS. LOCKARD: 15:51
Q. That has been your prior testimony, has it 15:51
not? 15:51
A. It -- it -- 15:51
MR. STANOCH: Objection to form. Misstates 15:51
prior testimony. 15:51
Go ahead. 15:51
THE WITNESS: It -- again, my concern isn't 15:51
about who did testing. You are allowed to not do 15:51
testing. My -- I have not opined in my report that 15:51
not doing testing is a problem. Okay. I haven't said 15:51
that. 15:52
The regulation allows you in 21 CFR 84 -- 15:52
211.84 to not do testing or to do testing. You are -- 15:52
it's to your discretion. You are allowed. I have 15:52
never said that you are not allowed. 15:52
I'm saying that they didn't compare 15:52
chromatography, the actual physical chromatograms. 15:52
If they -- they are supposed to compare it 15:52

Page 237

if they don't do testing. If they do testing, they 15:52
are supposed to take those chromatograms with them and 15:52
compare it on-site during an audit. I don't see 15:52
either of those things. 15:52
BY MS. LOCKARD: 15:52
Q. Don't -- don't these values demonstrate to 15:52
you that Teva reviewed its chromatography in order 15:52
to compile this chart? 15:52
MR. STANOCH: Objection. 15:52
THE WITNESS: These -- these numbers do not 15:52
come from a chromatogram. They come from a 15:52
calculation that is based on absorbance from the 15:52
chromatogram. The chromatogram -- you know, you do a 15:52
calculation to come up with these numbers. This 15:52
number does not represent what the chromatogram looks 15:52
like. 15:53
And in this matter, they found -- you know, 15:53
there were peaks in the chromatogram that appeared to 15:53
not be -- you know, to not be there or not properly be 15:53
there. That would not be reflected in these numbers. 15:53
This trend analysis does not include review 15:53
of actual chromatograms. This is review of results 15:53
that have been calculated. 15:53
BY MS. LOCKARD: 15:53
Q. Okay. Understanding your testimony now -- 15:53

Page 238

now that I have shown you the results of Teva doing its testing, are there any revisions you would like to make to your report where you criticize Teva for not doing its own testing? 15:53

MR. STANOCH: Objection. 15:53

THE WITNESS: No. There is no revisions. 15:53

BY MS. LOCKARD: 15:53

Q. Would you like to go through the annual reports for the subsequent in the prior years in order to see that Teva was doing its own testing in each of those according to its annual reports, or would that be a waste of our time today? 15:53

MR. STANOCH: Objection. 15:53

THE WITNESS: I do not need to see that. I'm not saying it's a waste of time, but I do not need to review the rest of that data. 15:53 15:54

BY MS. LOCKARD: 15:54

Q. Okay. So just so I understand, your testimony is that performing chromatograms that are required to generate these results and recording the results from those tests is not reviewing chromatograms? 15:54

MR. STANOCH: Objection. Asked and answered. 15:54

Go ahead. 15:54

Page 239

THE WITNESS: The question doesn't make sense. 15:54

What I'm saying is that these values do not come from chromatograms [witness indicates document]. 15:54

The graphic picture -- 15:54

BY MS. LOCKARD: 15:54

Q. They -- 15:54

A. -- there are absorbances from that picture that are used in a calculation to come up with this number. This number does not come from a chromatogram. 15:54

Q. It comes from chromatography testing; right? 15:54

A. It's -- it's a calculation. 15:54

Q. Okay. But it comes from chromatography? The numbers come from the chromatography? 15:54

A. Not this number [witness indicates document]. There is an absorbance that comes from the chromatography, but this number is not that number. This is a calculated number [witness indicates document]. 15:55

Q. They cannot generate these test results without performing chromatography; isn't that right? 15:55

A. Agreed. They -- hopefully they did not produce these numbers without actually performing tests. 15:55

Page 240

What I am saying is I expect Teva to review the chromatography for potential anomalies. 15:55

Not whether they pulled the right absorbance off the chromatogram and did a calculation and then did trend analysis on those numbers. This is a secondary level. 15:55

My concern in -- and what I opined in the report is that, if a strange peak or some anomaly appeared in the graphic chromatography, that's what they should question. 15:55

I never said that they needed to question numbers that met specification. We have talked about specifications. I have no concern with the specifications. My concern is did they review graphic chromatography, and these numbers do not reflect that. 15:55 15:56

Q. Okay. You haven't seen anything to indicate whether they did or did not review the graphic chromatography? 15:56

MR. STANOCH: Objection to form. 15:56

THE WITNESS: I have not seen -- that is my concern that I have not seen something that demonstrates that they did what Novartis did and reviewed actual chromatography. 15:56

Page 241

BY MS. LOCKARD: 15:56

Q. You haven't seen anything in the evidence that indicates they didn't review the chromatography, the chromatograms? 15:56

MR. STANOCH: Objection to form. 15:56

THE WITNESS: Again, I would expect there to be a reference to -- to actual physical review of chromatography. I don't have evidence that they didn't review chromatography, but there's certainly no evidence that they did. 15:56

And these numbers do not reflect that [witness indicates document]. 15:56

BY MS. LOCKARD: 15:56

Q. Well, you also, prior to today, assumed that Teva did not do its own chromatography testing and that it just copied the results from ZHP's certificate of analysis. 15:56 15:57

So you are making assumptions based on the lack of evidence either way in this case, aren't you? 15:57

A. No, I'm not. 15:57

MR. STANOCH: Objection to form. Misstates the opinions of his report and testimony. 15:57

BY MS. LOCKARD: 15:57

Q. You're assuming the negative due to the 15:57

Page 242

lack of the evidence that you haven't seen? 15:57
MR. STANOCH: Same objection. 15:57
THE WITNESS: No, I'm not. 15:57
MS. LOCKARD: All right. I think I am done 15:57
with the questioning. I think we have a couple of 15:57
folks on the line who want to ask questions. 15:57
MR. STANOCH: Okay. Who is next? 15:57
MS. LOCKARD: So who is next? 15:57
MS. BRANCATO: This is Alexia Brancato from 15:57
Kirkland & Ellis on behalf of Torrent. 15:57
Can you hear me okay? 15:57
MS. LOCKARD: Let's turn you up a little bit 15:57
because you are a little dim. 15:57
MS. BRANCATO: Thanks for doing that. 15:57
While that is going on, do you have 15:57
something in front of you where you can see electronic 15:57
documents? 15:58
THE WITNESS: No, I don't. 15:58
MR. HARKINS: We should go off the record 15:58
for a moment. 15:58
MS. BRANCATO: Why don't we go off the 15:58
record, please. 15:58
THE VIDEOGRAPHER: Okay. Going off record 15:58
at 3:58 p.m. 15:58
(Brief recess.) 15:58

Page 243

THE VIDEOGRAPHER: And we are back on the 15:59
record at 4:00 o'clock p.m. Start of Media Number 7. 16:00
EXAMINATION 16:00
BY MS. BRANCATO: 16:00
Q. Mr. Russ, my name is Alexia Brancato. 16:00
Like I said, I represent Torrent in this 16:00
lawsuit, and I am with the law firm of Kirkland & 16:00
Ellis. Thank you for your time so far today. I'm 16:00
going to try to use my time as expeditiously and 16:00
efficiently as possible. 16:00
Have you ever heard of Torrent 16:00
Pharmaceuticals Limited or Torrent Pharma Inc. prior 16:00
to your engagement in this matter? 16:00
A. No. 16:00
Q. And do you understand the distinction 16:00
between Torrent Pharmaceuticals and Torrent 16:00
Pharma Inc.? 16:00
A. No. 16:00
Q. Okay. When I refer to "Torrent" today in 16:00
my questions, I'm talking about Torrent 16:00
Pharmaceuticals Limited, which is the actual 16:00
manufacturer of the finished dose Valsartan product. 16:00
Do you understand that? 16:00
A. I do. 16:00
Q. Mr. Russ, I want to confirm you have 16:01

Page 244

three opinions with regard to Torrent; correct? 16:01
MR. STANOCH: Objection. 16:01
THE WITNESS: What opinions do you believe I 16:01
have with Torrent? 16:01
BY MS. BRANCATO: 16:01
Q. Sure. 16:01
We can look at your report. I believe 16:01
it's Exhibit 8, and we can start on Paragraph 108. 16:01
Do you see it says [as read]: 16:01
"Torrent's behavior and actions 16:01
related to supplier qualification, 16:01
monitoring and evaluation of ZHP's 16:01
ZnCl2 process change does not comply 16:01
with the cGMP requirement to establish 16:01
the reliability of their API supplier 16:01
as based on [... the CFR]." 16:01
Do you see that? 16:01
A. I do, yes. 16:01
Q. This is one opinion you are offering with 16:01
regard to Torrent; correct? 16:01
A. It is. 16:01
Q. Let me ask you this question: 16:01
How many opinions are you offering with 16:02
regard to Torrent? 16:02
MR. STANOCH: Objection. Vague. 16:02

Page 245

THE WITNESS: We can talk about this 16:02
opinion, if you would like, and then move to what 16:02
other opinion you think that I'm also offering. 16:02
BY MS. BRANCATO: 16:02
Q. No. I'm just wondering if you know off 16:02
the top of your head how many opinions you are 16:02
offering with regard to Torrent. 16:02
A. No. I need to go through the report and 16:02
then detail that back to you. If you have questions 16:02
on opinions I have made in the report, I'd be happy 16:02
to discuss those with you. 16:02
Q. And off the top of your head, can you list 16:02
the opinions that you have with regard to Torrent? 16:02
A. No. I have already stated that. 16:02
Q. All right. Let's start with what I 16:02
consider to be your second opinion for Torrent. 16:02
It's on Page 20 of your report. 16:02
Do you see that section is entitled "The 16:02
Contamination Went Undetected Because Torrent Never 16:02
Tested Any of the Sample Valsartan API Batches It 16:02
Received From ZHP"? 16:03
A. Yes. 16:03
Q. That is an opinion that you are making 16:03
with regard to Torrent; correct? 16:03
A. It is. 16:03

Page 246

Q. And, in fact, you say that Torrent never tested Valsartan API batches at multiple points in your report; isn't that correct? 16:03
A. It is. 16:03
Q. You testified earlier today that you had read Dr. Nagaich's report that Torrent issued in this case; correct? 16:03
A. I have. 16:03
Q. And after reading that report, do you have any changes to make to this opinion that we are looking at on Page 20? 16:03
A. No, I don't. The -- that expert states that testing was performed but references a couple of CofAs and a discussion he had with an employee. 16:04 There is no reference to his particular review of data that was tested by Torrent. 16:04
So until -- again, that documentation or -- there's no objective evidence that all this testing that is proposed in his report was actually performed. 16:04
Q. Are you aware that Dr. Jaiswal testified in his deposition that Torrent did, in fact, test every API batch received from ZHP? 16:04
A. The testimony -- deposition testimony was somewhat muddled in their -- it's difficult to 16:04

Page 247

follow. So it appeared to me that no testing was performed. 16:04
Q. Okay. Why don't we pull up -- I'm sorry. 16:04
MS. BRANCATO: What exhibit did we stop at if anyone knows over there? 16:04
THE REPORTER: This is the reporter. Or one second. 16:04
MR. STANOCH: I trust you. 16:04
MS. BRANCATO: I can start with 30 if that's easier. 16:05
THE REPORTER: Yes. That would be great. 16:05
MS. BRANCATO: Okay. Perfect. Thanks, Dayna. 16:05
Okay. So why don't we pull up the deposition transcript that's titled "2021.06.0526," please, Justin, and we'll mark that as Exhibit 30. 16:05
(Deposition Exhibit 30 was marked for identification and is attached hereto.) 16:05
MS. BRANCATO: And let's look at -- I'll get you the pdf page in just a second. 16:05
Pdf Page 38, please. 16:05
And I'm looking at Page 502 to 503 on the right-hand side. 16:06
Specifically Line [verbatim] 502, 24 to 503, 4. 16:06

Page 248

BY MS. BRANCATO: 16:06
Q. Do you see that in this section Dr. Jaiswal testifies [as read]: 16:06
"ANSWER: And as yesterday also I indicated, as part of, like, our own program, every batch was tested. I'm talking about the API batches being tested by us." 16:06
Do you see that? 16:06
A. I understand. Yes, I do see it. 16:06
Q. Did you consider Dr. Jaiswal statements that Torrent tests every API batch in forming your opinion that Torrent never tests any Valsartan API batch? 16:06
A. Again, as stated in previous testimony here today is my concern is not so much whether certain testing was performed but whether chromatography was reviewed and that comparative evaluation of chromatography with certificates of analysis and data associated with ZHP was performed. 16:07
Q. So the conversation that you were having with counsel for Teva, before we switched questioning over to me, related to chromatography review and comparing chromatographies between Torrent -- I am sorry -- between Teva and ZHP 16:07

Page 249

applies equally to Torrent, in your opinion; correct? 16:07
A. It does. 16:07
Q. Okay. So when your report says that Torrent never tested any of the sample Valsartan API batches, it should actually say, "Torrent never did a chromatography review and compared the results between what it found and what ZHP found"; is that right? 16:07
MR. STANOCH: Objection to form. 16:07
THE WITNESS: No, it's not. You know, a -- again, defense counsel -- defendant -- I'm sorry -- defendant expert witness's report only references a couple of CofAs and a conversation with an employee at Torrent to demonstrate that testing was performed. 16:08
That is insufficient for me to state that Torrent did testing. 16:08
BY MS. BRANCATO: 16:08
Q. When you say "defendants' expert witness," I am assume you are talking about Dr. Nagaich; right? 16:08
A. I -- I am. I apologize. The gentleman -- I forget the gentleman's name. 16:08
Q. No. I -- I just want to make sure we are talking about the same guy. 16:08

Page 250

A. We are. 16:08
Q. And when you say he referenced a couple of 16:08
CoAs, are those Torrent CoAs that you are speaking 16:08
of or the ZHP CoAs? 16:08
A. Torrent CoAs. 16:08
Q. So, in your opinion, Torrent CoAs are 16:08
insufficient to establish that Torrent was 16:08
preforming any testing on Valsartan API; is that 16:08
right? 16:08
MR. STANOCH: Objection to form. 16:08
THE WITNESS: It's insufficient to 16:08
demonstrate they tested all batches as is being stated 16:08
here by Mr. -- by the employee at Torrent. 16:09
BY MS. BRANCATO: 16:09
Q. Your opinion, though, on Page 20 is that 16:09
Torrent never tested any Valsartan batches; correct? 16:09
A. It is. 16:09
Q. And the CoAs that Dr. Nagaich cited -- and 16:09
I can pull them up if you want to look at them -- 16:09
established that Torrent did, in fact, test some 16:09
Valsartan API batches; correct? 16:09
A. It doesn't. It's just a CofA. It 16:09
could -- I need a reference to notebook references 16:09
or I would need to see the data. The data for all 16:09
lots. So it's insufficient as objective evidence 16:09

Page 251

that testing was performed. 16:09
Q. Okay. I just want to make sure I 16:09
understand. 16:09
Your opinion is that a CofA is 16:09
insufficient to prove that Torrent performed any 16:09
testing on Valsartan API; is that right? 16:09
MR. STANOCH: Objection. 16:09
THE WITNESS: Four CofAs that were 16:09
referenced are insufficient. CofAs alone are summary 16:10
documents. They are -- they don't demonstrate that 16:10
testing was actually performed. 16:10
BY MS. BRANCATO: 16:10
Q. In -- in your opinion, it's also 16:10
insufficient that the head of Torrent Quality 16:10
Assurance Group testified under oath that Torrent 16:10
does test every batch of Valsartan API; correct? 16:10
A. Yes -- 16:10
MR. STANOCH: Objection. 16:10
THE WITNESS: -- it's insufficient. 16:10
BY MS. BRANCATO: 16:10
Q. What specific documents do you -- in your 16:10
opinion, would be sufficient to establish that 16:10
Torrent does test any Valsartan API? 16:10
A. The raw data associated with those tests, 16:10
with those CofAs, which would include all of the 16:11

Page 252

chromatographic data, the raw data from the system, 16:11
test sample numbers, et cetera. 16:11
Q. The CoAs that were referred to in 16:11
Dr. Nagaich's report, the Torrent CoAs specifically, 16:11
your opinion is that they could reflect testing done 16:11
by some other company, not necessarily Torrent; is 16:11
that right? 16:11
A. I don't know that. It may be CofAs that 16:11
were performed by -- by Torrent themselves or it may 16:11
be transcriptions. Again, it's common for the 16:11
industry to transcribe from supplier CofAs on to 16:11
their own CofAs. It's a standard practice. 16:11
Q. Do you have any evidence that Torrent 16:11
transcribed ZHP CoAs on to a Torrent CoA in this 16:11
case? 16:12
A. I do not. 16:12
Q. Did you undertake a review of the ZHP CoAs 16:12
and Torrent CoAs and compare the two? 16:12
A. No. It wasn't germane to my report. 16:12
Q. You are not aware whether the ZHP CoAs and 16:12
the Torrent CoAs match exactly or have any 16:12
differences; correct? 16:12
A. This -- that wouldn't be the document I 16:12
would go to do comparative analysis. CofAs 16:12
comparison is -- is not what I had concerns with. 16:12

Page 253

As stated previously in my testimony, my 16:12
concern is did Torrent compare physical 16:12
chromatograms from raw data testing with those from 16:12
CHP. Either on-site or on some routine data review. 16:12
Q. Okay. And that's what I am trying to get 16:13
at. So let me -- let me try it this way: 16:13
Are you going to come to trial and tell 16:13
the jury Torrent never performed any testing of the 16:13
Valsartan API it received from ZHP? 16:13
MR. STANOCH: Objection to form. 16:13
Answer if you can. 16:13
THE WITNESS: I would say I don't have 16:13
objective evidence of that testing. The appropriate 16:13
primary record is objective evidence of that testing. 16:13
BY MS. BRANCATO: 16:13
Q. And I think I know the answer to this 16:13
question. But have you reviewed the 100,000-plus 16:13
documents Torrent produced in this case? 16:13
A. If it's on my list of -- that supports my 16:13
report, then I reviewed those documents. 16:13
Q. And that list does not include every 16:13
single document Torrent produced in this case; 16:13
correct? 16:13
A. I had sufficient documentation to arrive 16:13
at my opinions within my report. 16:13

Page 254

Q. Okay. That doesn't answer my question. 16:14
The list attached to your report does not include 16:14
every single document Torrent produced in this case; 16:14
correct? 16:14
MR. STANOCH: Objection. 16:14
THE WITNESS: I don't know if that is the 16:14
case. 16:14
BY MS. BRANCATO: 16:14
Q. You mentioned earlier that the CoA could 16:14
potentially be some kind of summary and it -- it's 16:14
not raw data that show actual testing. 16:14
What would the CoA be a summary of? 16:14
A. It's not potentially a summary; it is a 16:14
summary. It is values that come from the raw data 16:14
calculations that I have talked with counsel about 16:14
previously. It's a summary of that data. 16:15
Q. Let's look at Paragraph 112 of your 16:15
report, please. 16:15
A. Yes. 16:15
Q. You state [as read]: 16:15
"It appears that Torrent ultimately 16:15
employed reduced testing of ZHP's 16:15
valsartan API." 16:15
Do you see that? 16:15
A. Yes. 16:15

Page 255

Q. What is the basis for that statement? 16:15
A. Because data wasn't provided to me. So it 16:16
appears that Torrent employed a reduced testing 16:16
program, which is consistent with industry practice. 16:16
There is nothing wrong with that. 16:16
Q. When you say "reduced testing," do you 16:16
mean zero testing? Or what does "reduced testing" 16:16
mean here? 16:16
A. Reduced testing program is ideally you 16:16
must do an ID test regardless. 16:16
You can forego all other tests other than 16:16
those that are specifically needed for your 16:16
particular product, like, particle size, or if you 16:16
have water content specifications that are more 16:16
stringent than the supplier's, there may be some 16:16
other tests other than ID that you would perform. 16:16
But reduced testing is exactly that. I 16:16
don't necessarily do all of the tests that are on 16:16
the specification. I do a reduced number of those. 16:16
Q. So you have seen evidence that Torrent 16:16
does a reduced number of specifications at the very 16:17
least -- or, I am sorry -- a reduced number of 16:17
testing based on the specifications; correct? 16:17
A. No. My statement here is that it appears 16:17
that Torrent ultimately employed reduced testing. I 16:17

Page 256

say "appears" because raw data for testing of lots 16:17
received from ZHP wasn't provided to me in the 16:17
production. 16:17
Q. Okay. So you -- you don't actually have 16:17
any support for this statement; is that right? 16:17
MR. STANOCH: Objection. 16:17
THE WITNESS: No. It appears. I reviewed 16:17
and it appears that there's no data. So they were 16:17
using a reduced testing program potentially, which is 16:17
required -- you know, which is allowed within an -- an 16:17
industry practice. 16:17
It's not a -- an incorrect assumption or 16:17
something along those lines. It's normal to do 16:17
reduced testing or to not test all the drug substance 16:17
received. It's a standard-industry practice. 16:17
I say it appears they are following that 16:18
practice because I wasn't provided with any data. 16:18
BY MS. BRANCATO: 16:18
Q. Do you have any reason to doubt that 16:18
Torrent was at least doing identity testing on the 16:18
Valsartan API? 16:18
A. No. I have no reason to believe they 16:18
weren't doing ID. 16:18
Q. And what is your support for that 16:18
statement? 16:18

Page 257

MR. STANOCH: That's -- I am sorry. 16:18
Objection. Ambiguous. 16:18
THE WITNESS: ID testing is specifically 16:18
required in the regulation. And most firms do ID 16:18
testing upon receipt. 16:18
BY MS. BRANCATO: 16:19
Q. Let's look at the second sentence of 16:19
Paragraph 112. You say [as read]: 16:19
"...it did not test batches of 16:19
valsartan API it received from ZHP for 16:19
the purpose of qualifying the 16:19
reliability of the supplier when it 16:19
added ZHP to its product applications." 16:19
Do you see that? 16:19
A. I do. 16:19
Q. There's no citation for this statement, is 16:19
there? 16:19
A. There were no comparative testing data 16:19
that was provided, nor was there any statement in 16:19
any expert report or by any person deposed that they 16:19
did comparative testing. 16:19
Q. Okay. So you are concluding that 16:19
something did not happen because you did not see 16:19
evidence of it; correct? 16:20
MR. STANOCH: Objection. 16:20

Page 258

Go ahead. 16:20
THE WITNESS: If it -- if it's not 16:20
documented that it happened, then it didn't happen. 16:20
That's a standard industry practice as well. If it's 16:20
not written down, it didn't happen. 16:20
BY MS. BRANCATO: 16:20
Q. Do you see any emails or documents that 16:20
say, "Heads-Up. We are not going to test the 16:20
batches of the API for purposes of qualifying the 16:20
supplier"? 16:20
A. No. I did not see such an email. 16:20
Q. Paragraph 113 says [as read]: 16:20
"Torrent also did not monitor CoA 16:20
results with its own periodic 16:20
testing...and it did not test batches 16:20
when the change to ZnCl2 process was 16:20
executed." 16:21
Do you see that? 16:21
A. Yes. 16:21
Q. And is this similar to what we discussed 16:21
earlier that this opinion is based on the fact that 16:21
you haven't seen raw testing data? 16:21
A. There's no mention of any comparative 16:21
testing in any of the emails associated with the 16:21
change for Zinc chloride. 16:21

Page 259

Q. When you say "comparative testing," what 16:21
are you referring to? 16:21
A. Comparative testing is when I take the 16:21
chromatograms from the new process and I review them 16:21
against chromatograms from the old process. That 16:21
could either be -- that would be done as part of the 16:21
change control qualification of ZHP. 16:21
So that is what I am referring to here. 16:21
No mention of comparison -- comparative testing 16:21
which is support for that change. 16:21
Q. I think where I'm getting confused here is 16:21
that your report -- and sometimes in this 16:21
deposition -- you use the word "testing" very 16:21
broadly without any limitation. But it sounds like, 16:21
based on the testimony you have been giving over the 16:22
last hour, what you are mainly focused on is the 16:22
lack of comparative chromatogram testing or review; 16:22
is that right? 16:22
A. It is. 16:22
MR. STANOCH: And objection. The report 16:22
speaks for itself. 16:22
Go ahead. 16:22
MS. BRANCATO: Someone is not on mute on the 16:22
Zoom. If everyone can mute themselves, that would be 16:22
great. 16:22

Page 260

BY MS. BRANCATO: 16:22
Q. So in Paragraph 113 -- to make sure I am 16:22
super clear on this -- when you say "Torrent did not 16:22
test batches when the change to Zn2 -- ZnCl2 process 16:23
was executed," you were focused on the fact that 16:23
Torrent did not do those chromatogram comparison 16:23
testings that you have been talking about; correct? 16:23
A. Correct. 16:23
Q. And your opinion that Torrent did not do 16:23
that chromatogram comparison testing or review is 16:23
based on the lack of any evidence showing that they 16:23
did so; is that right? 16:23
A. That is correct. 16:23
Q. Keeping with Paragraph 113, the next 16:24
sentence says [as read]: 16:24
"These practices are industry 16:24
standard for monitoring the quality of 16:24
API material received from its 16:24
supplier." 16:24
And the next sentence [as read]: 16:24
"In not performing these actions, 16:24
Torrent failed to follow expected cGMP 16:24
as required by..." the regulation laid 16:24
out there. 16:24
Do you see that? 16:24

Page 261

A. I do. 16:24
Q. You stated earlier that the regulation 16:24
does not require anything except identity testing; 16:24
correct? 16:24
A. I did. And I -- again, I'm not referring 16:24
to identity testing or receipt testing. I'm 16:24
referring to comparative testing of chromatograms 16:25
for a change. 16:25
Q. Is there a specific regulation that 16:25
requires comparative testing for chromatograms for 16:25
changes? 16:25
A. No. There is not. I detailed the 16:25
expected requirements earlier in this report in 16:25
Paragraph 48 -- I'm sorry. I apologize. I'm sorry. 16:25
I would have to search it out in my report. 16:25
But I describe -- as part of the -- 16:25
comparative testing is used as part of initial 16:25
qualification and then also when a change occurs. 16:25
It normally is three batches of comparative testing. 16:26
I make this statement in the report. 16:26
Q. Okay. I want to make sure I'm 16:26
understanding. 16:26
Is there a specific regulation that you 16:26
can cite that requires comparative testing for 16:26
chromatograms for changes? 16:26

Page 262

A. There is no specific regulation. But this 16:26
is industry standard, which, again, as I have 16:26
described previously, is the little c, the Current 16:26
Good Manufacturing Practice, where reasonable, 16:26
prudent manufacturers have a certain practice and 16:26
it's broadly applied across the industry. It 16:26
becomes part of GMP. 16:26
So, no, there is not a specific 16:26
regulation, but this is a standard practice that 16:26
would be applied to all manufacturers and would be 16:26
an expectation of regulators and people like myself, 16:26
quality individuals within the industry. 16:26
Q. Okay. I understand that. I understand 16:26
that part of your report is based on industry 16:26
practice. 16:26
I'm just trying to understand what 16:26
specific regulations, if any, I should be looking at 16:27
to understand what you say Torrent did or didn't 16:27
violate. 16:27
A. The -- 16:27
Q. So let me ask you this. 16:27
A. Okay. 16:27
Q. Are the specific regulations that you 16:27
believe Torrent violated listed in your report? 16:27
A. They are listed in this paragraph. It is 16:27

Page 263

listed in this paragraph. 21 CFR 211.84(d)(2). As 16:27
an expectation that the manufacturer will establish 16:27
the re- -- reliability of the supplier. That's the 16:27
regulation. 16:27
How industry does that is through 16:27
comparative testing. That's how they meet this 16:27
requirement. So this is the requirement that is 16:27
being met. This is the regulation that is being met 16:27
by comparative testing. 16:27
Q. I understand that. I'm just trying to get 16:28
the numbers so I can -- 16:28
A. 21 CFR 211.84(d)(2). It's stated in this 16:28
paragraph. 16:28
Q. Understood. 16:28
Are there any other regulations that you 16:28
allege that Torrent violated? 16:28
A. Not -- 16:28
Q. Strike that. 16:28
Your report -- I'm trying to make this as 16:28
easy as possible for you. 16:28
If you think -- if it's your opinion that 16:28
Torrent violated certain regulations, are they all 16:28
listed in your report? 16:28
A. They are. And industry practices. 16:28
Q. Let's look at Page -- Paragraph 114, 16:28

Page 264

please. 16:29
A. Okay. 16:29
Q. Do you see that it says [as read]: 16:29
"If Torrent had done any testing of 16:29
ZHP?s API itself or by an unbiased 16:29
third party, they likely would have 16:29
been able to detect any unexplained 16:29
peaks in the residual solvents testing 16:29
chromatograms." 16:29
Do you see that? 16:29
A. I do. 16:29
Q. You use the word "likely." Sitting here 16:29
today, you can't say with certainty that, if Torrent 16:29
had done a chromatogram comparison that you are 16:29
focused on, it would have identified unexplained 16:29
peaks. 16:29
MR. STANOCH: Objection to form. 16:29
THE WITNESS: I -- I don't know that. 16:29
BY MS. BRANCATO: 16:29
Q. The certificate of analysis that are -- we 16:30
have been talking about today from Torrent that are 16:30
referenced in Dr. Nagaich's report, do you recall 16:30
seeing any unexplained peaks or references to 16:30
unexplained peaks in those CoA? 16:30
A. No. And they wouldn't be documented 16:30

Page 265

there. That's not the -- that's not the place for 16:30
something like that. It would be review of the 16:30
chromatograms themselves, which is done in a 16:30
laboratory by quality compliance individuals in the 16:30
laboratory to assure that chromatography is 16:30
meeting -- what is called a "standard 16:30
chromatograph," which is normally in the method. 16:30
This is done in the laboratory. This 16:30
is -- it has nothing to do with the CofA. 16:30
Q. Let's back up to your first opinions that 16:31
we were talking about earlier, which is 16:31
Paragraph 108. 16:31
You see it says [as read]: 16:31
"Torrent's behavior and actions 16:31
related to supplier qualification, 16:31
monitoring and evaluation of" -- this 16:31
again -- "ZnCl2 process does not comply 16:31
with the cGMP requirement...." 16:31
A. Yes. 16:31
Q. What specifically about Torrent's behavior 16:31
and action related to supplier qualification does 16:31
not comply with the cGMP? 16:31
A. They didn't establish the reliability of 16:31
the supplier based on other elements that I have 16:31
already stated in the report. The report stands for 16:31

Page 266

itself on what I expect those requirements to be. 16:31
There's no evidence that they performed any of those 16:31
types of evaluations or actions. 16:32
Q. Can you point me to where in your report 16:32
you list the types of evaluations or actions that 16:32
you would have expected a supplier qualification to 16:32
have? 16:32
A. It's entire Section D, "Overview of GMP 16:32
Requirements for Oversight of API Suppliers." 16:32
Q. Okay. So it's your -- your opinion is 16:32
that Torrent did not undertake any of the actions 16:32
listed in your entire Section D; is that right? 16:32
A. I believe that Torrent had a technical 16:32
agreement or a supply agreement or a quality 16:32
agreement that would be an element. 16:32
Other than that, I didn't see that they 16:32
had any other supplier management vehicles to assure 16:32
the reliability of the supplier. 16:32
Q. Okay. So let me ask you a few questions 16:33
about that. 16:33
Have you seen the Torrent quality 16:33
agreement with ZHP? 16:33
A. I believe so, yes. 16:33
Q. And do you have any opinions or 16:33
qualifications, statements to make about the 16:33

Page 267

substance of that agreement with ZHP? 16:33
A. No. I have no concerns with that. 16:33
Q. Okay. I'm trying to nail down exactly 16:33
what behavior or action you think that Torrent did 16:33
not undertake that it should have undertaken in 16:33
supplier qualifications. 16:33
And what I understand your testimony to 16:33
be -- and correct me if I am wrong -- is that 16:33
Torrent did not do anything that it should have 16:33
done, as you list in Section D, with the exception 16:33
of a quality or technical agreement; is that right? 16:33
A. That is my opinion. 16:34
Q. In Paragraph 108, you go on to say that -- 16:34
talk about monitoring and evaluation of ZHP?s ZnCl2 16:34
process change. 16:34
What behavior and actions should Torrent 16:34
have undertaken with regard to ZHP's ZnCl2 process 16:34
change to comply with the Valsartan, in your 16:34
opinion? 16:34
A. Certainly comparative testing, which is 16:34
defined in Paragraph 49. 16:34
Q. Anything else? 16:34
A. Evaluation and input from audits. As I 16:35
understand it, Torrent performed audits of ZHP but 16:35
didn't -- didn't do that in an appropriate 16:35

Page 268

frequency. 16:35
Q. Anything else? 16:35
A. Not other than what is already listed in 16:35
the report. 16:35
Q. I understand that you want to refer back 16:35
to your report -- and maybe you can point me to a 16:35
specific paragraph -- but I'm asking about 108 and 16:35
trying to get a list of what you think Torrent 16:35
should have done because it's not clear from this 16:35
particular paragraph -- and the rest of the report 16:35
goes back and forth between Torrent and Teva, and 16:35
I'm not quite sure which applies to which. 16:35
So in Paragraph 108, you talk about 16:35
monitoring and evaluation that Torrent should have 16:35
done on the ZnCl2 process. 16:36
And my question is what specific behaviors 16:36
or actions should they have taken that would have 16:36
complied with the ZHP. So far you have listed 16:36
comparative testing, defined in Paragraph 49, and 16:36
more frequent audits. 16:36
Is there anything else? 16:36
MR. STANOCH: Objection. 16:36
THE WITNESS: Everything that is listed in 16:36
Paragraph D [verbatim]. 16:36
///

Page 269

BY MS. BRANCATO: 16:36
Q. Section D, is that what you are referring 16:36
to? 16:36
A. I'm sorry. Section D. Yes. Forgive me. 16:36
This section in any way is not directed at 16:36
either Teva or Torrent. This is the requirements 16:36
for oversight of the supplier. 16:37
Q. Okay. So your opinion is that Torrent did 16:37
not take the actions you prescribe in Section D with 16:37
regard to "monitoring and evaluating ZHP's ZnCl2 16:37
process change"; correct? 16:37
MR. STANOCH: Objection to form. 16:37
THE WITNESS: It is. Well, in general, not 16:37
just the process change, but in general for the 16:37
supplier for ZHP, they didn't follow appropriate 16:37
qualification practices. 16:37
Again, the only clarification that I have 16:37
already stated is that they did have a quality 16:37
agreement, which is an element that should be in 16:37
place. And I don't have any concerns with that. 16:37
BY MS. BRANCATO: 16:37
Q. Okay. So is it your opinion that after 16:37
the -- the process change that ZHP undertook for the 16:37
ZnCl2 process, Torrent should have basically 16:38
re-qualified ZHP as a supplier via the steps and the 16:38

Page 270

things you lay out in Section D? 16:38
A. It is. That's the standard industry 16:38
practice. That at a change you would re-qualify, 16:38
re-evaluate. 16:38
Q. And I understand that you are saying it is 16:38
a standard industry practice, but is there a 16:38
specific detail or regulation that requires that? 16:38
MR. STANOCH: Objection. 16:38
Go ahead. 16:38
THE WITNESS: As I have stated previously, 16:38
the way I establish -- there is a direct regulation 16:38
21 CFR 211 84(d)(2). 16:38
The way I establish the reliability of a 16:38
supplier is through what I have described in Section D 16:38
of this report. That is the standard industry 16:38
practice. This is what most manufacturers or all 16:38
manufacturers would be held to at some level by 16:38
myself, by themselves as self-regulators. 16:38
And FDA has the expectation to see these 16:39
items as well. 16:39
BY MS. BRANCATO: 16:39
Q. Okay. Again, I fully understand your 16:39
industry practice opinion, and I -- I get that you 16:39
are saying that this is something Torrent should 16:39
have done based on industry practice. I just want 16:39

Page 271

to make sure I am not missing a piece of the 16:39
regulation. 16:39
Is there a specific detail or regulation 16:39
that requires requalification of a supplier after a 16:39
process change in manufacturing? 16:39
MR. STANOCH: Objection to form. 16:39
THE WITNESS: There's not a specific 16:39
regulation in either 210 or 211. Again, the way that 16:39
the GMP is -- is implemented in the industry is 16:39
through Current Good Manufacturing Practice. 16:39
These practices that prudent, reasonable 16:39
manufacturers employ become the GMP even though they 16:39
are not detailed directly in the regulation. 16:39
This is in case law as well. 16:39
BY MS. BRANCATO: 16:39
Q. I understand you are not going to be 16:40
testifying about the content of case law in this 16:40
lawsuit; correct? 16:40
MR. STANOCH: Objection to form. 16:40
THE WITNESS: No. Of course not. But this 16:40
is what drives industry's use of "current" in Current 16:40
Good Manufacturing Practice. Industry standard is 16:40
equal to GMP regulation. 16:40
BY MS. BRANCATO: 16:40
Q. In Paragraph 107 on Page 19 towards the 16:40

Page 272

bottom you say that [as read]: 16:40
"...Torrent never received sample 16:40
batches...." 16:40
Do you see that? 16:40
A. 107? 16:40
Q. Yes. It's on the screen, if that's 16:40
helpful. 16:40
A. Oh. 16:40
[Witness reviews document]. 16:40
Okay. I see that. 16:41
Q. What do you mean by "sample batch"? 16:41
A. Again, samples of the new process prior to 16:41
receiving anything. Those would be samples. 16:41
So ZHP or the -- Torrent or a manufacturer 16:41
would request samples, not commercial receipts but 16:41
samples of the new process material to do 16:41
comparative testing. 16:41
Q. And is it a requirement in the regulation 16:41
to get a sample batch or is that a best practice 16:41
industry standard? 16:41
MR. STANOCH: Objection. 16:41
THE WITNESS: Again, without -- I am sorry. 16:41
MR. STANOCH: Objection. 16:41
Go ahead. 16:41
THE WITNESS: Without a sample I can't do 16:41

Page 273

testing. So it's not only an industry practice, it's 16:41
required. I can't do testing without a sample. 16:41
BY MS. BRANCATO: 16:41
Q. I think we might be talking past each 16:42
other. 16:42
A. Sure. 16:42
Q. Does the CFR require that a manufacturer 16:42
obtain a sample batch of API after a process change 16:42
from its API supplier? 16:42
MR. STANOCH: Objection to form. Asked and 16:42
answered. Vague. Ambiguous. 16:42
Go ahead. 16:42
THE WITNESS: There's no direct regulation 16:42
from 21 CFR 210/211. I have already described the 16:42
concept of industry practice and how that relates to 16:42
GMP. 16:42
BY MS. BRANCATO: 16:42
Q. So the last sentence of Paragraph 107 says 16:43
[as read]: 16:43
"...Torrent merely relied on the 16:43
declaration it received from ZHP 16:43
regarding genotoxic impurities." 16:43
Do you see that? 16:43
A. I do. 16:43
Q. Is it your opinion that it is never in 16:43

Page 274

line with cGMP to rely on declarations from suppliers about genotoxic impurities? 16:43
MR. STANOCH: Objection to form. 16:43
THE WITNESS: No. It's perfectly normal to rely upon any certification from a supplier. 16:43
However, I trust and verify. 16:43
So when I go for an audit, I need to see the objective records or evidence that supports the statement, in this case a genotoxic impurity statement. 16:43 16:44 16:44
When I review audit reports that were performed by Torrent, there is no mention that the auditor did any verification of any objective evidence that supports these statements. 16:44 16:44 16:44 16:44
BY MS. BRANCATO: 16:44
Q. Do you know off the top of your head how many -- strike that. 16:44 16:44
Do you know whether you reviewed all of the audit reports that were performed by Torrent on ZHP? 16:44 16:44 16:44
MR. STANOCH: Objection. 16:44
THE WITNESS: I reviewed the audit reports that are referenced in my report. 16:44 16:44
BY MS. BRANCATO: 16:44
Q. And sitting here today, you don't know 16:44

Page 275

whether that is all of the audit reports or just some of them; is that right? 16:44 16:44
MR. STANOCH: Objection. 16:44
Go ahead. 16:44
THE WITNESS: I can't at this point say that it -- there's no evidence that I have, based on any of that reporting, that I don't have all the audit reports that were provided. It was what was provided to me in production. I base my opinions off of those reports. 16:44 16:44 16:45 16:45 16:45 16:45 16:45
BY MS. BRANCATO: 16:45
Q. Look at Paragraph 106. 16:45
Do you see in the first sentence it says that [as read]: 16:45 16:45
"...Torrent could not afford to challenge or reject ZHP's supply because ZHP was Torrent's only supplier of valsartan API." 16:45 16:45 16:45 16:45 16:45
A. Yes. 16:45
Q. What is that opinion based on? 16:45
A. That opinion is based on my experience that a sole source supplier leaves a firm with a very problematic issue when something occurs with that supplier and they no longer have material to make product and support their revenue. 16:45 16:45 16:45 16:45 16:45 16:45

Page 276

I have held these positions of leadership supporting quality and compliance for many firms, and I do that also as a third-party consultant. 16:46 16:46 16:46
A sole sourced supplier is a very problematic area for quality decisions. It's based on my opinion and my experience. 16:46 16:46 16:46
Q. In your experience, what percentage of finished dose manufacturers have more than one API supplier that are qualified for a particular drug? 16:46 16:46 16:46
A. I couldn't possibly give you a percentage, but certainly the idea -- ideal goal is to assure that I have alternate suppliers in the event that there is an issue with a supplier. That's within -- all of the firms that I have ever worked with, that is a goal is to have multiple suppliers. 16:46 16:46 16:46 16:46 16:46 16:46 16:46
Q. In all of the firms you have ever worked with, has every firm achieved that goal to have multiple suppliers for API for any one particular drug? 16:47 16:47 16:47 16:47
A. No. Certainly many -- you know, many manufacturers are -- have only a single supplier because that's all that is available to them or that's all they had developed relationships with. All I'm stating here is that leaves the firm in a precarious position when a problem arises at that 16:47 16:47 16:47 16:47 16:47 16:47

Page 277

supplier. 16:47
Q. And a cGMP does not require a finished dose manufacturer to qualify multiple API suppliers for one given drug; correct? 16:47 16:47 16:47
MR. STANOCH: Objection. 16:47
THE WITNESS: No, it does not. 16:47
BY MS. BRANCATO: 16:48
Q. Further on in Paragraph 106, you say that [as read]: 16:48 16:48
"Having a sole source of API applies undue pressures on an organization to accept lower quality API...." 16:48 16:48 16:48
Do you see that? 16:48
A. I do. 16:48
Q. Is that also based on your experience? 16:48
A. Extremely. I personally -- 16:48
Q. Have you ever seen -- 16:48
A. I personally have been in this position on multiple occasions. 16:48 16:48
Q. And in those multiple occasions, does the company that you worked for have lower quality API? 16:48 16:48
MR. STANOCH: Objection to form. 16:49
THE WITNESS: I'm just stating here that I have been in the position where undue pressure or -- has been presented to the organization because of a 16:49 16:49 16:49

Page 278

sole supply. Undue pressure to receive material that doesn't meet all of the GMP requirements that one would expect. 16:49

BY MS. BRANCATO: 16:49

Q. And in your experience, do the companies you work for accept the material that doesn't meet all of the GMP requirements given that undue pressure? 16:49

MR. STANOCH: Objection to form. 16:49

THE WITNESS: Not under my watch. 16:49

BY MS. BRANCATO: 16:49

Q. Are you offering any opinions about the quality of ZHP Valsartan API? 16:49

MR. STANOCH: Objection to form. Vague. 16:49

But go ahead. 16:49

THE WITNESS: No. 16:49

BY MS. BRANCATO: 16:49

Q. Are offering anything about Torrent's motivation in accepting ZHP Valsartan API? 16:50

MR. STANOCH: Objection to form. 16:50

Go ahead. 16:50

THE WITNESS: I certainly am in this paragraph. 16:50

BY MS. BRANCATO: 16:50

Q. And are you also offering an opinion about 16:50

Page 279

the pressures that Torrent faced in accepting the ZHP Valsartan API? 16:50

MR. STANOCH: Objection. 16:50

Go ahead. 16:50

THE WITNESS: It appeared to me from these documents and then also from the testimony of Mr. Jaiswal that this type of pressure existed in their culture. 16:50

BY MS. BRANCATO: 16:50

Q. When you say "this type of pressure existed in their culture," what do you mean? 16:50

A. The pressure to potentially accept products or not to alienate a supplier who sole sourced, not to -- 16:50

Q. When you say "their culture" -- go ahead. Sorry. 16:50

A. Their culture of -- when I -- sorry. It's -- I refer to the compliance culture, the culture compliance of the organization, which is an assessment of the spirit of compliance of how -- what the priority of quality in compliance is in the organization. That can be attacked when marketing concerns are -- pressurize an organization, especially around a sole sourced supplier. 16:50 16:51

Q. Okay. I'm going to back up to my 16:51

Page 280

question. 16:51

So the answer is yes. You are offering an opinion about the pressures that Torrent faced in accepting the Valsartan API; is that right? 16:51

MR. STANOCH: Objection to form. 16:51

Go ahead. 16:51

THE WITNESS: My opinion on this is stated here in Paragraph 106. 16:51

BY MS. BRANCATO: 16:51

Q. And I'm asking the question because I am not sure what 106 is trying to tell me. So I am asking you today. 16:51

Are you going to come to trial and offer an opinion about the pressures that Torrent faced in accepting ZHP Valsartan API? 16:51

MR. STANOCH: Objection to form. 16:51

THE WITNESS: I apologize that you don't understand Paragraph 106. But this is what I would state at trial. Exactly what is listed here. 16:52

BY MS. BRANCATO: 16:52

Q. And to make sure I understand what is listed in 106 combined with the testimony you gave a minute ago, you do believe that there was undo pressure in Torrent's compliance culture to accept ZHP Valsartan API; is that right? 16:52

Page 281

MR. STANOCH: Objection to form. Misstates the opinions. 16:52

Go ahead. 16:52

THE WITNESS: I am stating that the documents I reviewed, that are referenced here in this paragraph, led me to the conclusions I have drawn in this paragraph. 16:52

BY MS. BRANCATO: 16:53

Q. If we look at the last sentence of 106. Do you see that? 16:53

A. Yes. 16:53

Q. Are you opining that Torrent didn't follow the cGMP because it only had one API supplier? 16:53

A. No. 16:53

Q. Are you offering any opinions about why Torrent, in your opinion, didn't follow cGMPs? 16:53

MR. STANOCH: Objection to form. Asked and answered multiple times. 16:53

Go ahead. 16:53

THE WITNESS: I'm not sure what GMP you are referring to, if you could be specific. 16:53 16:54

BY MS. BRANCATO: 16:54

Q. I am referring to all of the cGMPs that you talk about in your report and in this deposition. I am just trying to understand if you 16:54

Page 282

are offering an opinion about why Torrent didn't follow cGMP. 16:54
MR. STANOCH: Objection. 16:54
Go ahead. If you could -- 16:54
THE WITNESS: In general, no. 16:54
BY MS. BRANCATO: 16:54
Q. What do you mean when you say "in general"? 16:54
A. If you are saying why -- what was the problem in their culture, in their compliance culture that led them to make poor decisions around GMP that I have identified in my report, the reason for that, I have -- I have not opined on that, nor do I have any further opinion other than what I have described here in 106. 16:54
Q. At the bottom of 106, you also say [as read]: 16:54
"Questioning ZHP about their DMF deficiency and other compliance problems at their facility." 16:55
Do you see that? 16:55
A. Correct. 16:55
Q. What DMF deficiency are you referring to? 16:55
A. There was a notified -- as I recall from the documentation review that I performed, there was 16:55

Page 283

a DMA -- or DMF deficiency, a ZHP DMF deficiency that affected a Torrent application. And then the compliance problems are elements identified in their audit reports. 16:55
Q. Okay. I'm going to separate those just to make sure I am understanding. So the DFM deficiency was on ZHP's part; correct? 16:55
A. There is -- yeah. Which affects Torrent's application because it's referred in their application. The DMF -- 16:55
Q. And -- 16:55
A. -- is a constituent part of the ANDA from Torrent, even though they don't have control over it. It's submitted as a constituent part. 16:56
So if there is a deficiency on the DMF, it affects their application. And what I am saying here is this pressure may have caused them not to pressure ZHP about DMF deficiencies or about compliance problems at the facility because they didn't want to agitate their supplier. 16:56
Again, a typical problem when you are sole sourced. 16:56
Q. So are you saying that Torrent didn't follow up or question ZHP about their DMA -- DMF deficiency? 16:56

Page 284

A. I haven't given specific reference to that. I am stating that it appears that they did not or that they -- 16:56
Q. And that's when you did not? 16:56
A. -- may have not. 16:56
Q. Can you say that last part again? I didn't catch it. 16:57
A. Just that these types of sole source causes one to not follow up necessarily on DMF -- or deficiencies and on compliance problems in a facility. 16:57
This is, again, an opinion and experience of mine over the 28 years that I have been practicing in the -- in the industry. 16:57
Q. Have you seen any evidence that Torrent did or did not follow up or question ZHP about their DMF deficiency? 16:57
MR. STANOCH: Objection to form. Compound. Confusing. 16:57
Go ahead. 16:57
THE WITNESS: I -- I have not -- give a reference here. So I don't have a document that I have referred to. I, at this point in the deposition, can't go research that now. 16:57
///

Page 285

BY MS. BRANCATO: 16:57
Q. And let's take the second half about compliance problems at their facility. 16:57
Are you referring to ZHP's facility? 16:57
A. Yes. I am referring to ZHP in the -- in the sentence. 16:58
Q. What specific compliance problems are you referring to that Torrent did not follow up with ZHP about? 16:58
A. Those identified in their audit reports from a risk perspective. 16:58
Q. Are you talking about all audit reports that you reviewed from Torrent or a specific audit report? 16:58
A. I am talking about compliance problems that were in their audit reports that I referenced in my report. 16:58
Q. Your report only references one audit, which we'll come to. 16:58
So does this opinion refer back to that one audit? 16:58
MR. STANOCH: Objection. Misstates the report. 16:58
Go ahead. 16:58
THE WITNESS: It refers to the observations 16:58

Page 286

that have been identified in reports that are referenced in my report. Yes. 16:58 16:59

BY MS. BRANCATO: 16:59

Q. You are not citing any particular audit reports in this paragraph at the end of 106; correct? 16:59 16:59 16:59

A. No, I am not. 16:59

Q. Back to the top of 106 in the sentence that says [as read]: 16:59 16:59

"Torrent sought out a valsartan API supplier such as ZHP in order to accomplish its goal of reducing its API costs...." 16:59 16:59 16:59

Do you see that? 16:59

A. Yes. 16:59

Q. Are you offering an opinion as to why Torrent purchased Valsartan API from ZHP specifically? 16:59 16:59 16:59

MR. STANOCH: Objection to form. 16:59

THE WITNESS: I'm only stating what was stated in the email that's referenced. 17:00 17:00

BY MS. BRANCATO: 17:00

Q. Why is the expense of the ZHP Valsartan API relevant to your opinions about Torrent's compliance with cGMPs? 17:00 17:00 17:00

Page 287

A. Because it demonstrates to me that revenue and pricing concerns are a part of the compliance decision process at Torrent. That cost was a major factor for them. That was the main goal. Based on the email that is referenced here, that's what it sounds like to me. 17:00 17:00 17:00 17:00 17:00 17:00

And, again, based on my experience, that exhibits a compliance culture that has problems, that is deficient when pricing is the most important element. 17:00 17:00 17:01 17:01

Q. So is it your opinion that any time that cost is a major factor for a manufacturer the compliance culture has problems? 17:01 17:01 17:01

MR. STANOCH: Objection to form. Mischaracterizes testimony. 17:01 17:01

Go ahead. 17:01

THE WITNESS: When I see areas of concern as I have noted throughout the report, along with this type of a statement in an email, yes, it does give me pause and concern that there is a problem with the compliance culture. 17:01 17:01 17:01 17:01 17:01 17:01

BY MS. BRANCATO: 17:01

Q. In your experience when cost is a concern for a manufacturer, does that automatically result in cGMP violations of that manufacturer? 17:02 17:02 17:02

Page 288

MR. STANOCH: Objection to form. 17:02

THE WITNESS: More often than not. 17:02

BY MS. BRANCATO: 17:02

Q. Do you have any particular examples from your experience where cost was a concern with the company you were working at and that led to cGMP violations? 17:02 17:02 17:02 17:02 17:02

MR. STANOCH: Objection to form. 17:02

And I just want to caution the witness not to divulge any specifics that would be subject to a non-disclosure or similar agreement. But if you can, go ahead. 17:02 17:02 17:02 17:02

THE WITNESS: I was going to say I am not at liberty to describe anything like that. 17:02 17:02

BY MS. BRANCATO: 17:02

Q. Let me try to ask it a different way. 17:03

In your experience -- strike that. 17:03

Let's look at Paragraph 118 of your report. 17:03 17:03

Do you see that this is in the section entitled "Torrent's Inadequate Use of Third-Party Inspectors to Audit ZHP's Manufacturing Facilities..."? 17:03 17:03 17:03 17:03 17:03

A. Yes. 17:03

Q. Paragraph 118 specifically calls out a third-party auditor, Dr. Jian Yang. 17:03 17:03

Page 289

Do you see that? 17:03

A. I do. 17:03

Q. And you also talk about Dr. Yang in Paragraph 119; correct? 17:04 17:04

A. I do. 17:04

Q. And in Paragraph 115 to 120 there are no references to any other auditors or audit reports specifically; correct? 17:04 17:04 17:04

A. Unless otherwise noted there. 17:04

Q. I'm not sure what that means. 17:04

A. If I have -- 17:04

Q. In paragraph -- 17:04

A. If I haven't referenced it here -- if I have referenced only one audit, then that's what has been referenced. 17:04 17:04 17:04 17:04

Q. Are you aware of any other -- strike that. 17:04

If there's no other audits or auditors referenced here, are you not presenting any opinions on those other audits or auditors that Torrent may have used? 17:04 17:04 17:04 17:04 17:04 17:04

MR. STANOCH: Objection to form. Really confusing about "here" and "audit" and "auditors" and this paragraph versus anywhere else. 17:04 17:04 17:05 17:05

So objection. Form. 17:05

Page 290

THE WITNESS: I only refer to the audit activity and the auditor that I'm describing here. 17:05
BY MS. BRANCATO: 17:05
Q. I just want to make sure I'm understanding the scope of your report with regard to Torrent's auditing reports and auditors. 17:05
This section focuses on Dr. Yang, and one audit report that she [verbatim] issued. 17:05
Do you expect to come to trial and issue other opinions with regard to other auditors and other audit reports that Torrent may have issued for ZHP? 17:05
MR. STANOCH: Objection to form. The "audit reports" and whether it's one or not. 17:05
But go ahead. 17:05
THE WITNESS: I would offer opinions on any audit reports that have been provided to me, whether I have referenced them in my report or not. 17:06
BY MS. BRANCATO: 17:06
Q. Okay. So you may come to trial and talk about an auditor that is not listed in Paragraph 115 to 120; correct? 17:06
A. I can't say that today. I only found it germane to reference what I have shown here in this section. 17:06

Page 291

Q. Sitting here today, do you have concerns about any other auditors that Torrent used for ZHP? 17:06
MR. STANOCH: Objection to form. "Any other auditors" for any other audits over what time period. Lacks specificity -- specificity. Vague. Ambiguous. 17:06
If you can answer, Mr. Russ. 17:06
THE WITNESS: Not at this time. I don't have any other -- I don't have any other opinions than what I have placed in the report right now. 17:06
BY MS. BRANCATO: 17:07
Q. Sitting here today, are you aware of whether there are other audits conducted by Dr. Yang on behalf of Torrent of ZHP? 17:07
MR. STANOCH: Objection to form. Vague. "Other audits"? Other than what? 17:07
If you can answer, go ahead. 17:07
THE WITNESS: Again, what I -- 17:07
BY MS. BRANCATO: 17:07
Q. I'm just going to ask -- hang on, Dr. -- Mr. Russ. 17:07
MS. BRANCATO: The speaking objections are getting a little bit out of hand right now. I just want to wrap this up as much you do. So I'm trying to go as quickly as possible. So if we could keep the objections just to form, foundation, et cetera, 17:07

Page 292

further. 17:07
MR. STANOCH: Objection. Lack of foundation of the number of audits. 17:07
Objection. Vague and ambiguous as to which audit and other audits. 17:07
Objection. Vague and ambiguous as to time period. 17:08
Mr. Russ, if you can answer, go ahead. 17:08
THE WITNESS: Again, I have -- I formed my opinions on the documents that have been referenced here in this report for this section. 17:08
BY MS. BRANCATO: 17:08
Q. I'm wondering if, sitting here today, you are aware of any other audits Torrent conducted of ZHP that were not done by Dr. Yang? 17:08
MR. STANOCH: Objection. 17:08
Go ahead. 17:08
THE WITNESS: Not at this time. I'm not aware of audits that were performed other than what I have referenced here at this moment. 17:08
BY MS. BRANCATO: 17:08
Q. This section refers to a Torrent document that ends in -10961. 17:08
Do you see those -- that reference in that paragraph? 17:08

Page 293

A. I do. 17:08
MS. BRANCATO: Can we pull up that document, please, Justin. And I think it's Exhibit 31 that we'll mark it as. 17:08
(Deposition Exhibit 31 was marked for identification and is attached hereto.) 17:09
BY MS. BRANCATO: 17:09
Q. Mr. Russ, is this a document that you cite in your report at Paragraph 116 to 118? 17:09
A. This -- 17:09
MR. STANOCH: There is no Bates on -- on the screen, but it may just be small for us. So that's all I'm noting for the record. 17:09
Okay. That is helpful. 17:09
Can you see it? 17:09
THE WITNESS: Yep. Thank you. 17:09
It is. 17:09
MS. BRANCATO: And if we could go to pdf Page 12, please, Justin. 17:09
BY MS. BRANCATO: 17:09
Q. Mr. Russ, is this the specific page you are relying on in the statements you make in 116 to 118 or are there other pages as well? 17:09
MR. STANOCH: Objection. Given that he doesn't have the document in front of him. 17:09

Page 294

But if you can answer -- and if you need the copy, that is her bad.

THE WITNESS: I -- I can't state which page. I reviewed the entire document in consideration for referencing it. I looked at the entire document.

MS. BRANCATO: Sorry. Justin, I think we should actually be on Page 13 of the pdf. Apologies.

BY MS. BRANCATO:

Q. Mr. Russ, does this page look familiar?

A. This is Page 11.

Q. Yes. 11 of 35. Does it look familiar to you?

A. [Witness reviews document].

If there's a section of it you could highlight for me. I cannot read it unfortunately. It's too small.

Q. Sure.

MS. BRANCATO: Why don't we zoom in on the first paragraph.

THE WITNESS: Is there a specific question you have on this page that's -- in regard to the section on Torrent's audit? Is there something specific here you want to ask me?

MR. STANOCH: She'll ask the questions, Mr. Russ. It's okay.

Page 295

BY MS. BRANCATO:

Q. I just want to make sure you were familiar with this page before I ask you my next few questions.

MR. STANOCH: Objection. No question pending.

BY MS. BRANCATO:

Q. Or with this paragraph entirely.

A. I have read the paragraph.

MR. STANOCH: Objection. There is no -- there is no question pending.

BY MS. BRANCATO:

Q. Do you see the observation 1d and the sentence that precedes it?

A. [Witness reviews document].

Okay.

Q. In writing your report and citing this document on Paragraph 116 to 118, is this the observation you are generally relying -- or referring to?

A. Can we go to the observation, and I'll read it and verify it for you.

MS. BRANCATO: Justin, can you go to pdf Page 29, please.

And then it will be 27 of 35 at the bottom.

Page 296

Perfect.

And if you could zoom in on the second half of the document.

BY MS. BRANCATO:

Q. Mr. Russ, do you see these observations?

A. [Witness reviews document].

This is -- isn't about auditors except that last paragraph in d) [as read]:

"Your Vice President of Quality stated you did not train third party vendors to conduct" -- and then I guess it's on the next page -- "audits."

MS. BRANCATO: Justin, can you do -- that's perfect. Thank you.

THE WITNESS: "Qualification of audits."

BY MS. BRANCATO:

Q. Do you see observation 1d?

A. Yes. The last statement in 1d.

Q. Is this -- is this the observation you are relying on when you talk about this document in 116 to 118 of your report?

A. It is.

MS. BRANCATO: Let's look at this document that ends in -4362, please. And we're going to mark that as Exhibit 32.

Page 297

(Deposition Exhibit 32 was marked for identification and is attached hereto.)

BY MS. BRANCATO:

Q. Mr. Russ, do you see this is the July 18th, 2017, letter from the FDA to Torrent?

A. I acknowledge it's a letter. And on FDA letterhead.

Q. Do you recall reviewing this document when you were putting together your report?

A. If it's referenced in my materials considered. Then I opened the document and reviewed it.

Q. I'm asking if you recall reviewing it, sitting here today?

A. Not today.

MR. STANOCH: Objection to that.

But that's fine.

BY MS. BRANCATO:

Q. Let's look at pdf Page 57, please.

MS. BRANCATO: And, Justin, if you could zoom on "Voluntary Corrections" and everything underneath there, that would be great.

BY MS. BRANCATO:

Q. Mr. Russ, do you see that this is the section entitled "Voluntary Corrections" relating to

Page 298

an inspection concluded on May 20th, 2016? 17:15
A. Yes. 17:15
Q. And is that the same inspection that was 17:15
being referenced in Exhibit 31 that we just looked 17:15
at, the EIR? 17:15
A. It appears to be. 17:16
Q. And if we look at "Observation 1d," that 17:16
would be observation regarding vendor audit 17:16
qualifications that we were looking at in 17:16
Exhibit 31; correct? 17:16
A. It is. 17:16
Q. The FDA states here in this Exhibit 32 17:16
that Torrent requalified as a third-party auditor 17:16
Dr. Jian Yang on July 12th, 2016. 17:16
Do you see that? 17:16
A. I do. 17:16
Q. And ultimately FDA concluded that the 17:16
auditor, Dr. Yang, was qualified according to the 17:16
updated procedure; correct? 17:16
A. They were trained to the procedure after 17:16
they performed audits for Torrent. 17:16
They were still untrained at the time of 17:16
the audit. They were still not qualified as an 17:16
auditor at the time of the audit. 17:16
This just demonstrates that going forward, 17:16

Page 299

prospectively, post July 12th, 2016, they had been 17:16
qualified to the procedure. That's all this states. 17:17
Q. I understand your position. I am asking 17:17
you specifically the statement that FDA makes in 17:17
this document is [as read]: 17:17
"This auditor was qualified 17:17
according to the updated procedure and 17:17
had reviewed the audit checklist." 17:17
Correct? 17:17
MR. STANOCH: Objection. Not sure of what 17:17
the question is. 17:17
THE WITNESS: It states that she was trained 17:17
to their procedural checklist. This does not make an 17:17
auditor qualified, just that they understand their 17:17
procedure. That's all this is. 17:17
BY MS. BRANCATO: 17:17
Q. I understand that you want to interpret 17:17
this document, and I understand your position on it. 17:17
I am -- just want to make sure that we -- we're both 17:17
on the same page about what the FDA says in these 17:17
words. 17:17
It says, quote [as read]: 17:17
"The auditor was qualified according 17:17
to the updated procedure and had 17:17
reviewed the audit checklist. No 17:18

Page 300

discrepancies were noted." 17:18
Correct? 17:18
MR. STANOCH: Objection to form. Misstates 17:18
the document. 17:18
Go ahead. 17:18
THE WITNESS: It states that. But on -- 17:18
this is as of 7/12/2016. So anything done by this 17:18
auditor previous to that she would be considered 17:18
unqualified. 17:18
BY MS. BRANCATO: 17:18
Q. So last statement you said, "So anything 17:18
done by this auditor previous to that, she would be 17:18
considered unqualified." 17:18
That's your opinion, not what the FDA is 17:18
saying in Exhibit 32; correct? 17:18
A. FDA is purely verifying that they saw that 17:18
training was done as of 7/12/2016. They make no 17:18
statement about her retrospective qualification. It 17:18
just says that she reviewed the procedure and that 17:19
there was a training document for it. That does not 17:19
constitute a qualified auditor alone. 17:19
Q. This is -- 17:19
A. This is a review of the training record. 17:19
They are saying, "I reviewed a training record and 17:19
no discrepancies were noted." 17:19

Page 301

Q. Look at Paragraph 119, please, of your 17:19
report. 17:19
Do you see toward the end of this 17:19
paragraph you say [as read]: 17:19
"Torrent, appearing to be unfazed by 17:19
Dr. Yang's finding in 2015 and did 17:19
nothing to do follow-up with these 17:19
concerns." 17:19
A. Yes. 17:19
Q. There's no citation at the end of this 17:19
sentence or in this paragraph for that statement. 17:19
My question is what is the basis for that 17:20
statement? 17:20
A. That -- in response to the email that this 17:20
references, that there was no indication that they 17:20
took action based on the reports of issues that are 17:20
significant issues reported by their auditor. 17:20
There's no response provided or no other 17:20
further evaluation that was in the production that 17:20
states what follow-up specifically was done based on 17:20
these -- this list of information that the auditor 17:20
provided to management at Torrent. 17:20
Q. You said "no other further evaluation that 17:20
was in the production," do you mean the documents 17:20
that were provided to you and that are referenced in 17:20

Page 302

the back of your report? 17:20
A. Yes. 17:21
Q. In your opinion, what follow-up was 17:21
required of Torrent to comply with cGMP? 17:21
MR. STANOCH: Objection to form. 17:21
THE WITNESS: What I would expect is that 17:21
she's listed multiple items here that there will be 17:21
observations in an audit report that would represent 17:21
what this meant. There are no observations that are 17:21
specific to this comment. 17:21
So there's no follow-up because there's no 17:21
observation. 17:21
So how did Torrent respond to these comments 17:21
if they weren't in an audit report. Because Torrent 17:21
may follow up on their observations from an audit 17:21
report, but this doesn't appear in the audits that I 17:21
reviewed from 2015. Doesn't appear in the audit. So 17:21
how could Torrent follow up on it? 17:21
BY MS. BRANCATO: 17:21
Q. I see. I just want to make sure I am 17:22
understanding this. 17:22
So your statement is here that these three 17:22
statements from Dr. Yang, from an email, did not 17:22
appear in an audit report from the doctor; correct? 17:22
A. They -- 17:22

Page 303

MR. STANOCH: Objection to form. 17:22
Mischaracterizes the testimony. 17:22
Go ahead. 17:22
THE WITNESS: They -- they don't appear as 17:22
an audit observation that would then get follow-up. 17:22
These comments are then not documented with objective 17:22
evidence that supports the comments in an audit report 17:22
so that the firm could address a corrective action and 17:22
Torrent would have the opportunity to follow up on 17:22
that corrective action. 17:22
It's not in the audit report. It's a 17:22
comment in an email. So how did Torrent follow-up on 17:22
it. So I am saying they did nothing to follow up on 17:22
it. 17:22
BY MS. BRANCATO: 17:22
Q. So do you see evidence one way or the 17:22
other that Torrent did or did not do anything to 17:22
follow up on these concerns? 17:22
MR. STANOCH: Objection to form. Confusing. 17:22
Vague. Ambiguous. 17:22
Go ahead. 17:22
THE WITNESS: The vehicle for follow-up with 17:23
concerns with the supplier is an audit report, 17:23
observations in an audit report. If an observation 17:23
was not issued to the supplier, there's no corrective 17:23

Page 304

action and there is no ability to follow up on that. 17:23
BY MS. BRANCATO: 17:23
Q. And you saw no evidence that Torrent did 17:23
any kind of follow-up in any way regarding these 17:23
three findings from this email; is that right? 17:23
MR. STANOCH: Objection. Asked and 17:23
answered. 17:23
Go ahead. 17:23
THE WITNESS: I saw no observation in the 17:23
report. So, therefore, there was no opportunity to 17:23
follow up because there's no specific observation 17:23
that -- that revolves around these three statements 17:23
that were provided to management in email. 17:23
BY MS. BRANCATO: 17:23
Q. Could Torrent management not have taken 17:23
follow-up steps based on the email alone? 17:23
A. They certainly could have. But that's not 17:23
a formal GMP vehicle to do follow-up with a 17:23
supplier. It's through observations and an audit 17:23
report and corrective actions. That's how I track 17:24
that. That's the vehicle for GMP. 17:24
If they did something to address this, it 17:24
was outside of the GMP system because the GMP system 17:24
requires observations with corrective actions and 17:24
follow-up. 17:24

Page 305

Q. If Torrent did something to address these 17:24
three concerns from this email, is it still -- have 17:24
they still violated GMP because they didn't do 17:24
anything via an audit report with observations and 17:24
corrective action? 17:24
MR. STANOCH: Objection to form. Incomplete 17:24
hypothetical. 17:24
Go ahead. 17:24
THE WITNESS: Yes. Because the only vehicle 17:24
through which I do corrective and preventative action 17:24
is through an observation, a corrective action plan, 17:24
and a follow-up. That's the vehicle. Otherwise, it's 17:24
not documented. It's not tracked in a GMP system. 17:24
Audits are GMP systems. An email is not a 17:24
GMP system. 17:25
MS. BRANCATO: All right. Why don't we take 17:25
a break. 17:25
Let's go off the record. 17:25
THE VIDEOGRAPHER: Okay. Going off record 17:25
at 5:25 p.m. 17:25
(Brief recess.) 17:42
THE VIDEOGRAPHER: And we are back on the 17:42
record at 5:52 p.m. [verbatim]. 17:42
BY MS. BRANCATO: 17:42
Q. Mr. Russ, I have no further questions at 17:42

Page 306

this time. 17:42
THE WITNESS: Oh. Thank you. 17:42
MR. STANOCH: Next questioner, I guess. 17:42
MS. ROSE: I take it ZHP is next. 17:42
Anybody else? 17:42
MS. LOCKARD: I think you are the only one. 17:42
MR. STANOCH: I would think -- and there are 17:42
only 30 here; right? So it's just -- 17:42
MS. ROSE: Then I'll take over. 17:42
MR. STANOCH: Okay. Go ahead, Counsel. 17:42
17:42
EXAMINATION 17:42
BY MS. ROSE: 17:42
Q. Hi, Mr. Russ. How are you? 17:42
A. Hello. Thank you. 17:42
Q. My name is Nina Rose from Skadden, Arps, 17:42
and I am here representing the ZHP defendants in 17:42
this case. 17:43
You stated at the beginning of this 17:43
deposition that you do not intend to offer any 17:43
opinions about -- I am sorry. 17:43
You don't intend to offer any opinions at 17:43
trial about any defendants in the case other than 17:43
Teva and Torrent; correct? 17:43
A. That is correct. 17:43

Page 307

THE VIDEOGRAPHER: I am sorry. 17:43
BY MS. ROSE:
Q. And what about at facilities that --
(Simultaneously speaking.)
THE REPORTER: Wait one second.
MS. LOCKARD: Hold on.
MR. STANOCH: Counsel, wait.
MS. LOCKARD: Nina.
MR. STANOCH: We have a tech issue. 17:43
THE VIDEOGRAPHER: Can we go off the record 17:43
for a one moment? 17:43
MR. STANOCH: Sure. 17:43
MS. ROSE: How -- 17:43
MS. LOCKARD: We've got -- 17:43
THE VIDEOGRAPHER: Off record at 5:43 p.m. 17:43
(Brief recess.) 17:44
THE VIDEOGRAPHER: And we are back on the 17:44
record at 5:45 p.m. 17:45
MS. ROSE: Thanks. 17:45
BY MS. ROSE: 17:45
Q. Going back to my earlier question and in 17:45
light of your previous testimony earlier today, it 17:45
appears today that you do not intend to offer any 17:45
opinions at trial about ZHP? 17:45
MR. STANOCH: Objection to form. 17:45

Page 308

But go ahead. 17:45
THE WITNESS: That is correct. 17:45
BY MS. ROSE: 17:45
Q. And you are not offering any opinions 17:45
regarding ZHP's compliance with cGMP; correct? 17:45
A. No. 17:45
Q. I am sorry. I didn't catch that. 17:45
A. No. 17:45
Q. Earlier today you were asked about FDA 17:45
statements that it was not known by regulators or 17:45
the industry that NDMA could form during the 17:45
Valsartan manufacturing process. 17:45
And you made a comment that ZHP internal 17:45
documents indicated that the chemistry of NDMA 17:46
formation in Valsartan was well known. 17:46
Do you remember that? 17:46
A. I remember stating that ZHP documentation 17:46
about reaction chemistry associated with their 17:46
product. "Well known" I am not sure I stated. 17:46
Q. Okay. So what documents were you 17:46
referring to? 17:46
A. Their investigation document into how NDMA 17:46
or how nitrosamines formed in their product. I 17:46
can't reference the -- the Bates number, but I know 17:46
I have seen this document. 17:46

Page 309

Q. Okay. Were you referring to a document 17:46
that was created by ZHP after the identification of 17:46
NDMA in Valsartan in May, June of 2018? 17:46
A. Yes. This was created after it was 17:46
identified and characterized as nitrosamine. 17:46
Q. You haven't done any investigation of 17:47
whether the chemistry of NDMA formation in Valsartan 17:47
was well known prior to May 2018; is that correct? 17:47
A. No, I have not. And it's not germane to 17:47
my report. 17:47
Q. So you don't intend to offer any opinions 17:47
at trial regarding whether the chemistry of NDMA 17:47
formation in Valsartan was known prior to May 2018? 17:47
MR. STANOCH: Objection to form. 17:47
But go ahead. 17:47
THE WITNESS: No, I don't. 17:47
BY MS. ROSE: 17:47
Q. You made another comment earlier -- and I 17:47
hope I'm paraphrasing you correctly -- that ZHP may 17:47
have known about the presence of NDMA in Valsartan 17:47
prior to its identification by Novartis in May 2018, 17:47
but that you don't know if that's true. 17:47
Do you recall saying that? 17:47
MR. STANOCH: Objection. Form. 17:47
///

Page 310

THE WITNESS: Yes. I do recall saying that. 17:47
BY MS. ROSE: 17:47
Q. Do you intend to offer any opinion at 17:47
trial about what ZHP knew about the presence of NDMA 17:47
in Valsartan and when? 17:48
MR. STANOCH: Objection to form. 17:48
Go ahead. 17:48
THE WITNESS: No, I do not. 17:48
BY MS. ROSE: 17:48
Q. We were talking earlier about 17:48
Paragraph 106 of your report -- 17:48
A. Yes. 17:48
Q. -- and specifically the last sentence of 17:48
that paragraph. 17:48
A. Yes. 17:48
Q. Let me know when you are there. 17:48
A. I'm there. 17:48
MS. ROSE: Thanks, Justin. 17:48
BY MS. ROSE: 17:48
Q. You were being questioned earlier about 17:48
the last sentence in this paragraph that discussed 17:48
whether Torrent was questioning ZHP about their 17:48
DMF deficiency and other compliance problems at 17:48
their facility. 17:48
Do you recall that? 17:48

Page 311

A. Yes. 17:48
Q. The DMF deficiency that you are referring 17:48
to in the last sentence of the paragraph is that the 17:49
December 2010 deficiency that is referenced in 17:49
Paragraph 105? 17:49
A. [Witness reviews document]. 17:49
Yes. 17:49
Q. Is it correct that that deficiency did not 17:49
address Valsartan after the manufacturing process 17:49
changes at issue in this litigation? 17:49
MR. STANOCH: Objection. 17:49
But go ahead. 17:49
THE WITNESS: I need to review the document, 17:49
but I don't believe so. 17:49
BY MS. ROSE: 17:49
Q. Just to be clear, you don't believe that 17:49
the deficiency letter had anything to do with the 17:49
Valsartan API that was manufactured using the 17:49
manufacturing processes at issue in these -- in this 17:49
litigation? 17:49
MR. STANOCH: Objection. 17:49
Go ahead. 17:49
///
///
///

Page 312

THE WITNESS: Again, I -- without reviewing 17:49
the documents, again, I can't verify that, but I don't 17:50
believe so. 17:50
BY MS. ROSE: 17:50
Q. Do you know when the manufacturing process 17:50
changes at issue in this litigation took place? 17:50
MR. STANOCH: Objection. 17:50
THE WITNESS: I -- I would have to go 17:50
through the report and pull out a specific date when 17:50
they issued the change control. So I don't have that 17:50
off the top of my head. 17:50
BY MS. ROSE: 17:50
Q. But it says December 2010 deficiency was 17:50
issued prior to the change control for the 17:50
manufacturing process at issue. 17:50
You would agree that it would be 17:50
irrelevant to this case? 17:50
MR. STANOCH: Objection to form. 17:50
Go ahead. 17:50
THE WITNESS: It's not irrelevant to the 17:50
case in that -- especially to Paragraph 106, in that 17:50
I'm trying to describe here concerns with the 17:50
compliance culture at Torrent and their ability to 17:50
request information associated with the DMF. 17:50
So it's not that it's irrelevant. It's 17:51

Page 313

relevant to Torrent's compliance culture. It may be 17:51
irrelevant to the change to the Zinc chloride process, 17:51
but it's not irrelevant to Torrent's compliance 17:51
culture. 17:51
BY MS. ROSE: 17:51
Q. And going back to that last sentence of 17:51
106 when you talk about the compliance problems at 17:51
their facility -- 17:51
A. Yes. 17:51
Q. -- do you intend to offer any opinions 17:51
regarding compliance problems that -- at 17:51
ZHP facilities? 17:51
MR. STANOCH: Objection to form. 17:51
THE WITNESS: I do not. 17:51
MS. ROSE: Okay. That's it. That's all I 17:51
have. Thank you. 17:51
THE WITNESS: Thank you. 17:51
MR. STANOCH: All right. Let's take a quick 17:51
break. 17:51
THE VIDEOGRAPHER: Okay. Going off record 17:51
at 5:52 p.m. 17:51
(Brief recess.) 17:59
THE VIDEOGRAPHER: And we are back on the 17:59
record at 5:59 p.m. Start of Media Number 10. 17:59
17:59

Page 314

EXAMINATION 17:59
BY MR. STANOCH: 17:59
Q. Good evening, Mr. Russ. 17:59
A. Good evening. 17:59
Q. What is your opinion on whether the 17:59
factors establishing adulteration of Teva and 17:59
Torrent finished dose Valsartan product existed? 17:59
MS. LOCKARD: Objection. Vague. 17:59
THE WITNESS: The compliance failure 17:59
specifically around supplier quality assurance and 17:59
management for Teva and Torrent rose to the level of 17:59
product adulteration. 18:00
And that the ZHP product was adulterated -- 18:00
was identified as FDA as adulterated. And in 18:00
subsequent incorporation into Teva and Torrent 18:00
finished products, their products would also be 18:00
adulterated. 18:00
MR. STANOCH: I have no further questions. 18:00
Thank you. 18:00
18:00
FURTHER EXAMINATION 18:00
BY MS. LOCKARD: 18:00
Q. Mr. Russ, when you went on a break with 18:00
counsel, did you talk about your testimony with 18:00
respect to the products being adulterated? 18:00

Page 315

MR. STANOCH: Objection to form. 18:00
THE WITNESS: No. 18:00
BY MS. LOCKARD: 18:00
Q. Didn't you tell us earlier today that you 18:00
didn't intend to come to court and testify that the 18:00
products were adulterated? 18:00
MR. STANOCH: Objection to form. Misstates 18:00
prior testimony. 18:00
THE WITNESS: I don't believe I said I 18:00
wouldn't say that the products were adulterated. I 18:00
think the products do rise to the level of 18:00
adulteration. I said that it wasn't FDA's role alone 18:00
to call a product adulterated. 18:00
BY MS. LOCKARD: 18:00
Q. So what definition are you using in this 18:00
case to determine that Teva and Torrent's products 18:01
are adulterated? 18:01
MR. STANOCH: Objection to form. 18:01
THE WITNESS: I described this earlier in 18:01
testimony as it relates to ICH Q9: severity, 18:01
occurrence, and detection. 18:01
MS. LOCKARD: Okay. Let's take a break for 18:01
a minute. I'm going to get that document. Go off the 18:01
record for a second. 18:01
THE VIDEOGRAPHER: Going off record at 18:01

Page 316

6:01 p.m. 18:01
(Brief recess.) 18:01
THE VIDEOGRAPHER: And we are back on the 18:06
record at 6:07 p.m. Start of Media Number 11. 18:06
BY MS. LOCKARD: 18:06
Q. All right. Mr. Russ, so I am going to 18:06
mark as an exhibit the ICH guideline Q9 on quality 18:06
risk management. We'll mark this as Exhibit -- 18:07
THE REPORTER: Either 25 or 33. 18:07
MS. LOCKARD: Let's go with 33. 18:07
(Deposition Exhibit 33 was marked for 18:07
identification and is attached hereto.) 18:07
BY MS. LOCKARD: 18:07
Q. Take a look at that. 18:07
Is that the ICH guideline that you 18:07
referred to just a moment ago? 18:07
A. It's not the format. This is from 18:07
European Medicines Agency. 18:07
Q. Is it -- 18:07
A. This isn't the guidance from -- that FDA 18:07
promulgates. But, yes, this is the ICH guideline 18:07
for Q9. 18:07
Q. Is the content of the guideline 18:07
essentially the same whether it comes from the 18:07
European Medicines Agency heading or the FDA? 18:07

Page 317

A. I haven't done that verification. But I 18:07
can stipulate that it's -- the concepts are the 18:07
same. 18:07
Q. Okay. I'll give you a chance to look that 18:07
over. 18:07
You are familiar at least with this -- the 18:07
European Medicines Agency ICH guideline Q9 enough to 18:07
know that it's reasonably similar? 18:08
A. Yes. 18:08
Q. All right. Can you find for us there in 18:08
that document where the definition of adulteration 18:08
is found? 18:08
A. No. This document is not meant for that 18:08
purpose. This is a tool. And it's a tool that 18:08
would apply to any risk decision. 18:08
And adulteration is a decision of whether 18:08
a GMP concern has the risk of producing or creating 18:08
product adulteration. 18:08
This guideline does not talk about 18:08
adulteration, nor does it talk about any other 18:08
specific risk event. It lists tools and how one 18:08
uses those tools. 18:08
Q. Okay. So the ICH Q9 does not provide the 18:08
definition for adulteration that you are applying in 18:09
this case; correct? 18:09

Page 318

MR. STANOCH: Objection to form. 18:09
THE WITNESS: No, it does not. It provides 18:09
a tool by which I provide the risk of certain GMP 18:09
activities that rise to the level of adulteration. 18:09
BY MS. LOCKARD: 18:09
Q. Are you familiar with 21 USC Section 351 18:09
entitled "Adulterated drugs and devices"? 18:09
A. Yes. 18:09
Q. Okay. Let's make that the next exhibit. 18:09
THE REPORTER: 34. 18:09
MS. LOCKARD: 34. 18:09
(Deposition Exhibit 34 was marked for 18:09
identification and is attached hereto.) 18:09
BY MS. LOCKARD: 18:09
Q. All right. And this is, in fact, the 18:09
United States statute governing -- governing when a 18:09
drug or device shall be deemed to be adulterated; 18:09
correct? 18:09
A. Yes. 18:09
Q. Okay. And this is, in fact, the 18:09
United States' definition of adulteration for all 18:10
intents and purposes under the FDA's application of 18:10
the term "adulteration," is it not? 18:10
MR. STANOCH: Objection to form. 18:10
THE WITNESS: It is. 18:10

Page 319

BY MS. LOCKARD: 18:10
Q. Okay. And can you explain to me what 18:10
provision within USC 351 you believe applies to 18:10
Teva's manufacturing operations and quality systems 18:10
in this case that would deem them adulterated? 18:10
A. Section (B) [as read]: 18:10
"If it is a drug and the methods 18:10
used in, or the facilities or controls 18:10
used for, its manufacture, processing, 18:10
packaging, or holding do not conform or 18:10
are not operated or administered in 18:10
conformity with good manufacturing 18:10
practice...." 18:10
(a)(B). 18:11
Q. You are reading from Section (a) governing 18:11
[as read]: 18:11
"Poisonous, insanitary...ingredients 18:11
and adequate controls in manufacture"? 18:11
A. Yes. [As read]: 18:11
"If a drug -- if it is a drug and 18:11
the methods used in, or the facilities 18:11
or controls used for, its manufacture, 18:11
processing, packaging, or holding do 18:11
not conform to or are not operated or 18:11
administered in conformity with good 18:11

Page 320

manufacture practice to assure such 18:11
drug meets the requirements of this 18:11
chapter." 18:11
That's the definition of GMP adulteration. 18:11
Q. And that's the basis for your opinion? 18:11
MR. STANOCH: Objection. Form. Misstates 18:11
testimony. 18:11
BY MS. LOCKARD: 18:11
Q. That's the basis for your opinion that the 18:12
Teva drugs are adulterated under 21 USC Section 351? 18:12
MR. STANOCH: Objection. Objection. 18:12
Misstates testimony. 18:12
THE WITNESS: This states that GMP can cause 18:12
product adulteration. That's all this states to me. 18:12
I use the principles of risk management to 18:12
determine the relative risk of certain GMP violations 18:12
and how they would rise to product adulteration. 18:12
In this particular case -- and I have 18:12
already described previously in testimony today that 18:12
supplier quality management, as it relates to 18:12
oversight of a supplier that Teva and Torrent were 18:12
performing for ZHP, is a high-risk quality -- quality 18:12
system and GMP compliance aspect, and that failures in 18:12
this area, failures I have described in my report 18:12
would rise to the level of product adulteration. 18:12

Page 321

So it's a combination of these documents 18:13
that help me to arrive at that conclusion. 18:13
BY MS. LOCKARD: 18:13
Q. Mr. Russ, today when you were asked this 18:13
question on the record under oath, as you are right 18:13
now [as read]: 18:13
"QUESTION: Okay. So you are not -- 18:13
you are not going to give the opinion 18:13
that any of the product manufactured by 18:13
Teva was adulterated? 18:13
"ANSWER: No, I am not. I am not -- 18:13
I am only stating that the practice 18:13
they employed for supplier management 18:13
were sufficiently deficient that it 18:13
would have a high probability of 18:13
leading to product adulteration." 18:13
That was your testimony today; correct? 18:13
A. That is my testimony, and that is the same 18:13
testimony I'm providing now. 18:13
Q. Okay. So at trial you intend to testify 18:13
that the practices Teva employed for supplier 18:13
management were sufficiently deficient that it would 18:13
lead to a high probability of leading to product 18:13
adulteration? That's your testimony you are giving 18:14
today and at trial; correct? 18:14

Page 322

MR. STANOCH: Objection to form. 18:14
Mischaracterizes the testimony and the immediately 18:14
prior questioning. Asked and answered. 18:14
MS. LOCKARD: I'm not mischaracterizing the 18:14
testimony. I am quoting it directly from the 18:14
transcript that was given under oath today earlier. 18:14
MR. STANOCH: Okay. And you are ignoring 18:14
the portions that were under oath two minutes ago, 18:14
Counsel. 18:14
MS. LOCKARD: I'm ignoring the portion where 18:14
the testimony was changed after woodhousing with 18:14
counsel. 18:14
No. Thank you. I'm done. No further 18:14
questions. 18:14
MR. STANOCH: Inappropriate. 18:14
I'm going to share my screen real quick. 18:14
Can I do that? 18:14
Stand by. 18:14
18:14
FURTHER EXAMINATION 18:14
BY MR. STANOCH: 18:14
Q. Mr. Russ, can you see something on your 18:14
screen now? 18:15
A. Yes. I see the ZHP warning letter. 18:15
MR. STANOCH: And I'll mark this as the next 18:15

Page 323

exhibit in print form. 18:15
(Deposition Exhibit 35 was marked for 18:15
identification and is attached hereto.) 18:15
BY MR. STANOCH: 18:15
Q. And you are familiar with this FDA letter 18:15
to ZHP from November 29th, 2018? 18:15
A. I am. 18:15
Q. You reviewed it as part of the materials 18:15
considered for your opinions; correct? 18:15
A. Yes. 18:15
Q. When I last questioned you, you mentioned 18:15
something to the effect that the FDA had found that 18:15
the Valsartan API incorporated into Teva and Torrent 18:15
finished dose product met the conditions to 18:15
establish adulteration; is that right? 18:15
A. It is. 18:15
Q. And, in fact, the FDA -- do you recall -- 18:15
set forth exactly what was the basis for that in 18:15
this letter? 18:15
Do you see that? 18:15
A. Yes. 18:15
Q. And could you please read what the FDA 18:15
says about that. 18:15
A. [As read]: 18:15
"This warning letter summarizes 18:15

Page 324

significant deviations from current 18:16
good manufacturing practice, cGMP, for 18:16
active pharmaceutical ingredient API. 18:16
Because your methods, facilities, or 18:16
controls for manufacture, processing, 18:16
packaging, or holding do not conform to 18:16
cGMP, your API are adulterated within 18:16
the meaning of this 18:16
Section 501(a)(2)(b) of the Food, Drug, 18:16
and Cosmetic Act 21 USC 351(a)(2)(B)." 18:16
Which is what I referenced earlier. 18:16
Q. Right. 18:16
And am I correct that that statement, as 18:16
you have read it here today for us and the members 18:16
of the jury and the FDA's letter along with 18:16
everything else you have testified to about earlier, 18:16
are the bases for your opinion on whether the 18:16
factors establishing adulteration of Teva and 18:16
Torrent finished dose Valsartan product existed? 18:16
A. It is. 18:16
MR. STANOCH: Okay. Nothing further. 18:16
MS. ROSE: ZHP has a couple more questions, 18:17
but, Victoria, I defer to you. 18:17
MS. LOCKARD: One moment. 18:17
18:17

Page 325

FURTHER EXAMINATION 18:17
BY MS. LOCKARD: 18:17
Q. Okay. Mr. Russ, so now after 18:17
Mr. Stanoch's questioning, you are including the 18:17
basis for your opinion -- your new opinion in the 18:17
last hour that the Teva and Torrent products are 18:17
adulterated -- a new basis for that now at 6:17 at 18:17
the end of the day of this deposition is the FDA's 18:17
letter to ZHP indicating that ZHP's product was 18:17
adulterated because ZHP's facilities, methods, and 18:17
controls were lacking? 18:18
Is that your testimony? 18:18
MR. STANOCH: Objection to form. 18:18
Mischaracterizes the testimony. It's material 18:18
considered. The very first page of his report 18:18
discusses this. 18:18
Go ahead, Mr. Russ. 18:18
THE WITNESS: This just restates -- I do 18:18
consider this, and this just restates what the 18:18
regulation states. What -- what you just provided me 18:18
here states [witness indicates document]. 18:18
I have also stated within my report 18:18
specifically [as read]: 18:18
"FDA found ZHP's valsartan API 18:18
adulterated (and accordingly Teva and 18:18

Page 326

Torrent finished dose product incorporating that API.)" 18:18
I have already made this statement in my expert report. 18:18
BY MS. LOCKARD: 18:18
Q. So your testimony is that any API that was made -- strike that. 18:18
Your testimony is that any finished dose that was made from Valsartan API is adulterated because the API manufacturer received a letter from FDA? 18:18
MR. STANOCH: Objection to form. Mischaracterizes the testimony. 18:19
THE WITNESS: Not because they received a letter, but because the material was adulterated. 18:19
BY MS. LOCKARD: 18:19
Q. According to whom? 18:19
A. It's not according to whom. It's according to the GMP compliance of that particular material. It has nothing to do with who identified that. 18:19
It's reasonable for an industry professional like myself to look at what material was coming out of ZHP, Valsartan material, the issues that arose, and that that material is 18:19

Page 327

adulterated. 18:19
Whether FDA identified it as adulterated or not would not change my viewpoint on whether that material was adulterated. I'm not using FDA's statements or their letter. 18:19
I agree with their statements and their letter, and I have considered those in my own opinion. But that's my own opinion. 18:19
Q. So you are not relying on the letter to FDA indicating -- excuse me. Strike that. 18:19
You are not relying on the FDA letter to ZHP indicating their products were deemed adulterated in forming your opinion that Torrent and Teva's products were adulterated. 18:20
MR. STANOCH: Objection to form. Mischaracterizes the testimony. Misstates the report. 18:20
BY MS. LOCKARD: 18:20
Q. Is -- okay. I'll rephrase. 18:20
Is -- 18:20
A. I -- can I answer the question? 18:20
MR. STANOCH: She -- 18:20
BY MS. LOCKARD: 18:20
Q. Go ahead. 18:20
MR. STANOCH: She withdrew the question. 18:20
THE WITNESS: Okay. 18:20

Page 328

BY MS. LOCKARD: 18:20
Q. I didn't withdraw the question. 18:20
MR. STANOCH: Okay. 18:20
BY MS. LOCKARD: 18:20
Q. Go ahead. 18:20
A. I just wanted to say -- 18:20
MR. STANOCH: Same objections, though. 18:20
THE WITNESS: -- not alone. I considered that report, I considered these letters, but it's not the only consideration. 18:20
I have lots of industry experience. I have dealt with adulteration issues previously other than this matter. 18:20
Certainly, in my opinion, the problems with ZHP material coming out of that facility raise to the level of GMP adulteration. 18:20
And the oversight issues that I have identified in my report also cause -- and the fact that this material was incorporated into finished products also causes that to rise to the level of adulteration. 18:21
I have stated it clearly in my report. 18:21
Throughout the testimony I have also described what methodology I have used in order to make that determination. 18:21

Page 329

BY MS. LOCKARD: 18:21
Q. So I want to be very clear about this. 18:21
If your opinion is that Teva's product is adulterated because Teva failed to comply with cGMPs, that's one thing, and we can talk about it. 18:21
If your opinion is that Teva's product is adulterated because ZHP's supply was adulterated and not based on any activity of Teva, that is a very different issue. 18:21
And that is what I am trying to understand. Is your opinion based in any way as to Teva's product being adulterated -- is it based in any way on the letter to ZHP indicating their product was adulterated? 18:22
MR. STANOCH: Objection to form. Asked and answered. Mischaracterizes the testimony. 18:22
THE WITNESS: I have considered both of those things. 18:22
And, again, I have stated in Paragraph 2 that, because FDA identified that, I considered that. It's not the sole consideration. I stated it in my report. It's right there. Paragraph 2, last sentence. 18:22
BY MS. LOCKARD: 18:22
Q. Paragraph 2 of your report -- 18:22

Page 330

A. [As read]: 18:22
"As a result of the FDA found ZHP's 18:22
valsartan" -- 18:22
Q. Excuse me. May I finish? 18:22
A. -- "API adulterated...." 18:22
Yeah. Sorry. 18:22
Q. The last sentence of Paragraph 2 says, 18:22
[as read]: 18:22
"I have also found that these 18:22
conditions existed prior -- years prior 18:22
to the eventual valsartan recalls 18:22
beginning in 2008 [verbatim]" -- 18:22
A. I apologize -- 18:22
Q. -- "'18." 18:22
A. -- the second-to-the-last sentence. 18:22
Q. Okay. The second-to-the-last sentence -- 18:23
let's just -- we'll just read from the -- from the 18:23
middle. 18:23
A. Yeah. 18:23
Q. [As read]: 18:23
"As a consequence of the 18:23
contamination of ZHP's valsartan API 18:23
and the cGMP failures at ZHP, (as well 18:23
as Teva's and Torrent's own 18:23
cGMP-related failures), Teva's and 18:23

Page 331

Torrent's finished dose valsartan 18:23
products distributed and sold in the 18:23
United States were manufactured in a 18:23
way that was not cGMP compliant." 18:23
A. Correct. 18:23
Q. [As read]: 18:23
"As a result the FDA found ZHP's 18:23
valsartan API adulterated (and, 18:23
accordingly Teva and Torrent finished 18:23
dose product incorporate that API)." 18:24
The fact of the matter, though, Dr. -- or 18:24
Mr. Russ, is that FDA never found Teva and Torrent's 18:24
finished dose product incorporating that API to be 18:24
adulterated, did they? 18:24
A. And, again, I -- they haven't, that I am 18:24
aware, of in a statement. 18:24
And, again, I have stated already in 18:24
testimony that that is not their role to identify 18:24
what is adulterated or not. It is -- that -- 18:24
because we do not need to wait for FDA to say 18:24
something is adulterated to determine that it's 18:24
adulterated. 18:24
It is not FDA's role, in my experience or 18:24
opinion, that I need to wait for FDA to make a 18:24
statement. 18:24

Page 332

To me, based on what I have reviewed in 18:24
this report, it's clear to me that the -- 18:24
incorporating this material into Teva and Torrent's 18:24
finished product makes that product adulterated. I 18:24
have stated that here as a summary. 18:25
And I have stated that it's based on 18:25
violations of GMP associated with Torrent and Teva, 18:25
and that it's based on FDA statement around ZHP's 18:25
material. 18:25
That's my opinion. And that is consistent 18:25
with how adulteration is identified in the industry. 18:25
Q. You told us earlier today that the FDA 18:25
doesn't deem product adulterated. That it is up to 18:25
the manufacturer to make that determination. 18:25
A. Agreed. It's their -- I am saying it's 18:25
not their role. I don't need to wait on FDA to 18:25
determine something is adulterated. 18:25
Q. But when FDA determines ZHP's product is 18:25
adulterated, that is burned and branded in this 18:25
case. When FDA decides not to send a similar letter 18:25
to Teva, which they easily could have done knowing 18:25
all the facts in this case, having investigated this 18:25
problem sufficiently to the fact that they sent ZHP 18:25
a letter, then it's not FDA's role in that instance? 18:26
MR. STANOCH: Objection to the form. 18:26

Page 333

Argumentative. Incomplete hypothetical. 18:26
Go ahead. 18:26
THE WITNESS: I'll refer to recall then. 18:26
BY MS. LOCKARD: 18:26
Q. Oh. Well, I don't -- 18:26
A. Recalls -- recalls are voluntary -- 18:26
MR. STANOCH: He's answering the question -- 18:26
THE WITNESS: Let me answer. 18:26
Recalls are voluntary. Teva and Torrent 18:26
decided to recall. It's a voluntary recall. They 18:26
were not forced through consent decree or through an 18:26
act of the court to recall products. They recalled 18:26
products because they agreed that their products 18:26
should not be on the market and were adulterated. 18:26
When I recall a product voluntarily, that to 18:26
me says that there were GMP compliance concerns or 18:26
specific SISPQ, strength, identity types of issues 18:26
that would cause me to recall a product voluntarily. 18:26
That means that I agree that this product is 18:26
adulterated. 18:26
BY MS. LOCKARD: 18:26
Q. So any product that is voluntarily -- 18:26
voluntarily recalled in the U.S. is therefore 18:27
adulterated? 18:27
MR. STANOCH: Objection to form. 18:27

Page 334

Mischaracterizes testimony. 18:27
THE WITNESS: If it's being recalled for a 18:27
GMP issue, then that GMP issue rose to the level of 18:27
product adulteration where I need to remove this 18:27
product from the market. 18:27
BY MS. LOCKARD: 18:27
Q. Did you see in the FDA notices regarding 18:27
their nitrosamine investigation that I showed you 18:27
today or in the -- in the recall notices that FDA 18:27
issued, where FDA instructed patients to continue 18:27
taking their medication? 18:27
A. I -- I didn't necessarily see that. And I 18:27
don't see how that is germane to my opinion that is 18:27
stated here in Paragraph 2. 18:27
This is what I have determined 18:27
adulteration in Paragraph 2. It has nothing to do 18:27
alone with what FDA says. It's an input. FDA's 18:27
consideration is an input for my determination of 18:28
whether I believe this to be adulterated. It's an 18:28
input, whether FDA says it or not. 18:28
If FDA did not give a statement to ZHP 18:28
about their adulteration, I would still consider 18:28
ZHP's material adulterated, and Teva and Torrent's 18:28
material adulterated. 18:28
Q. But under your theory of this case, FDA 18:28

Page 335

told patients in the United States to continue 18:28
taking adulterated medication contaminated with 18:28
impurities? That's -- that's consistent with your 18:28
opinion. 18:28
MR. STANOCH: Objection to form. Misstates 18:28
his opinion, testimony. 18:28
THE WITNESS: I never made any assertion to 18:28
that. During testimony or in my expert report. 18:28
BY MS. LOCKARD: 18:28
Q. Well, you know that FDA told the general 18:28
public to continue taking Valsartan medication when 18:28
the recall was announced. You saw that, surely, in 18:28
the documents you read? 18:29
A. I, again, don't have any opinion in my 18:29
report or in this testimony about the validity of 18:29
that comment from the FDA. 18:29
It's not my place to make a statement 18:29
there. I haven't made any statements about any of 18:29
that. 18:29
Q. You never worked at the FDA, have you? 18:29
A. No, I have not. 18:29
Q. You have never been hired as a consultant 18:29
for the FDA? 18:29
MR. STANOCH: Objection. Beyond the scope 18:29
of the recross. 18:29

Page 336

But go ahead. 18:29
THE WITNESS: No, I haven't. 18:29
MS. LOCKARD: He's talking about the 18:29
intentions of the FDA and what the FDA does and thinks 18:29
when they make announcements, when they, you know, 18:29
work with a company and voluntarily recalling a 18:29
product, when they deem something to be adulterated, 18:29
when they choose not to deem something to be 18:29
adulterated. 18:29
He's stepping into the shoes of the FDA. I 18:29
just want to know what experience he has. 18:29
THE WITNESS: I -- I -- 18:29
MR. STANOCH: Hold on. Hold on. Hold on. 18:29
Objection to the colloquy. Objection that 18:30
he is doing anything of the sort of saying what FDA 18:30
thinks. Mischaracterizes testimony. 18:30
But if you want the repeat the question, Ms. 18:30
Lockard, go ahead. My objection stands. 18:30
THE WITNESS: I could just state that 18:30
this -- this statement -- 18:30
MR. STANOCH: Wait. Wait until she asks a 18:30
question. 18:30
I think your question was something along 18:30
the lines of "Have you consult with the FDA" or 18:30
something. 18:30

Page 337

Right? 18:30
BY MS. LOCKARD: 18:30
Q. You have never been hired as a consultant 18:30
for the FDA? 18:30
MR. STANOCH: Same objections. 18:30
Go ahead. 18:30
THE WITNESS: No. 18:30
BY MS. LOCKARD: 18:30
Q. You have never been invited to give any 18:30
presentations at the FDA or for any FDA committees; 18:30
correct? 18:30
A. No. 18:30
MR. STANOCH: Same objections. 18:30
BY MS. LOCKARD: 18:30
Q. Have you ever applied for a job at the 18:30
FDA? 18:30
MR. STANOCH: Same objections. 18:30
THE WITNESS: No. 18:30
BY MS. LOCKARD: 18:30
Q. Have you ever authored any papers in 18:30
connection with anyone who works at the FDA? 18:30
MR. STANOCH: Same objections. 18:30
THE WITNESS: No. 18:30
MR. HONIK: We went through this eight hours 18:30
ago. 18:30

Page 338

MS. LOCKARD: I did not ask that question eight hours ago. I very specifically did not. 18:30 18:30 18:31

BY MS. LOCKARD: 18:31

Q. Have you ever consulted with anybody from the FDA about the circumstances or the facts of this case? 18:31 18:31

MR. STANOCH: Same objection. Well beyond the scope of recross. And asked and answered in terms of experience. 18:31 18:31 18:31

Go ahead. 18:31

THE WITNESS: No. 18:31

BY MS. LOCKARD: 18:31

Q. What is your bases for your opinions today about what the FDA does, thinks, decides, and why? 18:31 18:31

MR. STANOCH: Objection. Mischaracterizes testimony and opinions. Never testified any of those things. 18:31 18:31 18:31

THE WITNESS: I'll restate it again. 18:31

This, in Paragraph 2, is my opinion, and that input from FDA is considered. I have made no statements about FDA's behaviors, their actions, or decisions in my report or in the testimony. 18:31 18:31 18:31 18:31

BY MS. LOCKARD: 18:31

Q. So you don't intend to testify at trial as 18:31

Page 339

to any motivations by FDA or reasons why FDA chose not to issue a letter to Teva deeming its products adulterated? 18:31 18:31 18:32

MR. STANOCH: Objection to form. Beyond the scope of the recross and cross. And also improper because it's asking this witness what he may testify to at trial at some indeterminant point in time. 18:32 18:32 18:32 18:32

If you can answer, Mr. Russ, go ahead. 18:32

MS. LOCKARD: Well, I'll respond to that objection because we have been told this case is getting ready for trial in early summer. 18:32 18:32 18:32

MR. STANOCH: What is the date certain, Counsel? 18:32 18:32

MS. LOCKARD: I also am here to get the benefit of this witness's opinions, and today is the day to understand what he will be testifying to at trial. That is the point of the deposition. 18:32 18:32 18:32 18:32 18:32

MR. STANOCH: He doesn't decide what he testifies to at trial. I do. He's my witness. 18:32 18:32 18:32

You can answer, if you can answer. 18:32

MS. LOCKARD: Well, that is certainly true if you want to feed into the opinions, but I think I'm entitled to ask him what his opinions are today. 18:32 18:32 18:32 18:32

THE WITNESS: My opinion is in Paragraph 2. That's my opinion. I wrote this. FDA didn't write 18:32 18:32 18:32

Page 340

this. I didn't refer to FDA, necessarily. I used an input from FDA. I use inputs from FDA when I do all kinds of evaluations for audits, as it may be. 18:32 18:32 18:33 18:33

But I make no statements about regulatory or enforcement actions of FDA. That is not my role. My role here is exactly -- my opinion in this case that I would offer at trial is in Paragraph 2. 18:33 18:33 18:33 18:33 18:33

BY MS. LOCKARD: 18:33

Q. Because it would be outside your expertise to testify about what the FDA would do or why they took certain actions in this case; right? 18:33 18:33 18:33

MR. STANOCH: Objection to form. 18:33

THE WITNESS: It would be -- yes, absolutely. And I have made no statements to that effect. 18:33 18:33 18:33 18:33

BY MS. LOCKARD: 18:33

Q. Okay. So you will not be offering any opinion that the reason that FDA didn't issue a letter determining Teva's product to be adulterated was because they are too busy; they lack the resources; they only have, you know, so many hours in the day; anything like that? 18:33 18:33 18:33 18:33 18:33 18:33 18:33 18:33 18:33

MR. STANOCH: Well -- 18:33

BY MS. LOCKARD: 18:33

Q. You won't be saying anything like that; 18:33

Page 341

correct? 18:34

MR. STANOCH: Objection to form. Beyond the scope. Asked and answered from hours ago about resources and other things, which I know were discussed. Also vague and ambiguous. And argumentative. 18:34 18:34 18:34 18:34 18:34 18:34 18:34 18:34

But go ahead, Mr. Russ. 18:34

THE WITNESS: No. 18:34

MS. LOCKARD: Thank you. No more questions. 18:34

MS. ROSE: ZHP has a couple of questions. 18:34

18:34

FURTHER EXAMINATION 18:34

BY MS. ROSE: 18:34

Q. Mr. Russ, is -- you testified several times that you do not intend to offer any opinions about ZHP or its cGMP compliance; correct? 18:34 18:34 18:34 18:34

A. Correct. 18:34

Q. Do you intend to offer the opinion at trial that Valsartan API was adulterated at the time of sale? 18:34 18:34 18:34 18:34

A. I do. It's stated in my report in Paragraph 2. 18:34 18:34 18:34

Q. And what is -- strike that. 18:34

You stated at the deposition that the relevance standard for adulteration turns on 18:34 18:34

Page 342

conformity with cGMP; correct? 18:34
MR. STANOCH: Objection. Form. 18:34
Go ahead. 18:34
THE WITNESS: It does. It -- it relates to 18:35
351 in the statute definitions of adulteration. 18:35
BY MS. ROSE: 18:35
Q. And you stated that you do not intend to 18:35
offer any opinions that ZHP did not comply with 18:35
cGMP; correct? 18:35
A. I have stated that several times. 18:35
Q. Okay. I'm just trying to reconcile how 18:35
you intend to offer the opinion that Valsartan API 18:35
was adulterated at the time of sale when you are not 18:35
offering any opinion regarding ZHP's compliance with 18:35
cGMP if adulteration is tied to cGMP violations. 18:35
MR. STANOCH: Objection to form. That's 18:35
unintelligible. 18:35
THE WITNESS: I -- as I have said, I stated 18:35
my opinion in Paragraph 2. I don't know how many 18:35
other ways I can tell you what I would attest to or 18:35
testify to at trial. It's listed there in writing. 18:36
BY MS. ROSE: 18:36
Q. What is the basis for your opinion that 18:36
ZHP's Valsartan API was adulterated at the time of 18:36
sale? 18:36

Page 343

MR. STANOCH: Objection to form. Misstates 18:36
prior testimony. 18:36
THE WITNESS: It was identified to have a 18:36
genotoxic impurity. For me, that is adulterated 18:36
product. Period. End of sentence. No further 18:36
discussion or evaluation needed. 18:36
BY MS. ROSE: 18:36
Q. So the entirety of your opinion is that 18:36
Valsartan API manufactured by ZHP was adulterated at 18:36
the time of sale because it contained what you call 18:36
a genotoxic impurity and that's it? That is the 18:36
entire basis of your opinion? 18:36
MR. STANOCH: Objection to form. Misstates 18:36
the testimony and the report. We have talked now for 18:36
15 minutes about Paragraph 2 and et cetera. 18:36
But go ahead. 18:37
THE WITNESS: Yes. 18:37
BY MS. ROSE: 18:37
Q. Okay. I just want to be clear because 18:37
Paragraph 2 refers to the FDA finding that ZHP 18:37
Valsartan API was adulterated, which, as you stated 18:37
earlier, was the warning letter to the ZHP which was 18:37
issued after May of 2018; correct? 18:37
A. Correct. 18:37
Q. Beyond that one statement in Paragraph 2, 18:37

Page 344

I just want to know where else in your report did 18:37
you analyze the adulteration of ZHP's Valsartan API? 18:37
A. I do not. It's the only statement. 18:37
Q. I'm sorry? 18:37
A. I do not. It's the only statement as it 18:37
relates to Teva and Torrent's products, which is 18:37
what the subject of my report is on. 18:37
Q. Okay. And I'm not trying to beat a dead 18:37
horse. I really just want to make sure we 18:37
understand what your opinions are with respect to 18:38
ZHP. 18:38
If there is no analysis in your report 18:38
regarding the basis for an opinion that ZHP's API 18:38
was adulterated at the time of sale beyond the one 18:38
statement in Paragraph 2 stating that FDA found 18:38
ZHP's Valsartan API adulterated; is that correct? 18:38
MR. STANOCH: Objection. Form. Asked an 18:38
answered. Mischaracterizes testimony and the report. 18:38
Go ahead, if you can. 18:38
THE WITNESS: Yes. 18:38
BY MS. ROSE: 18:38
Q. To be clear, "Yes," that is the entire 18:38
basis for that opinion? 18:38
MR. STANOCH: Same objections. 18:38
///

Page 345

THE WITNESS: It is. 18:38
BY MS. ROSE: 18:38
Q. And you performed no other analysis of ZHP 18:38
or its cGMP compliance? 18:38
A. You have already identified that I have 18:38
not done so. And, no, I have not. 18:38
Q. And you have done no other analysis of 18:38
whether ZHP's Valsartan API was adulterated; 18:38
correct? 18:38
A. Correct. 18:39
MS. ROSE: Thank you. No other questions. 18:39
MR. STANOCH: Okay. I have nothing. Thank 18:39
you, Mr. Russ. 18:39
THE WITNESS: Thank you. 18:39
THE REPORTER: And that is Exhibit 25? 18:39
MS. LOCKARD: Yes. 18:39
Before we go off the record -- 18:39
MR. STANOCH: Yeah. That's fine. 18:39
MS. LOCKARD: Just a matter of housekeeping. 18:39
So we would like to mark this as Exhibit 25 because 18:39
there's a gap. 18:39
MR. STANOCH: Fine. 18:39
MS. LOCKARD: And this is the 18:39
acknowledgement and agreement we bound by the 18:39
protective order that is signed by the witness. 18:39

MR. STANOCH: I'll just state for the record that Mr. Russ had signed it before, but we didn't have a physical copy of it; so he graciously resigned it again today to make the record complete. Thank you. 18:39

MS. LOCKARD: No problem. As long as he complies. 18:39

(Deposition Exhibit 25 was marked for identification and is attached hereto.) 18:39

THE VIDEOGRAPHER: Okay. This will conclude today's video deposition. The time is approximately 6:40 p.m. 18:39

We're off the record. 18:39

(The following record was transcribed stenographically only with no video recording.) 18:39

THE REPORTER: Back on the record. 18:40

MR. STANOCH: Yeah. Back on the record. 18:40

We will read and sign. 18:40

Thank you. 18:40

THE REPORTER: Okay. 18:40

(Whereupon, at 6:40 p.m., the deposition of PHILIP JAMES RUSS was adjourned.)

--- oOo ---

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) SS.

I, Dayna Hester, C.S.R. No. 9970, in and for the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and the same is a true, correct, and complete transcript of said proceedings;

That if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript { } was { } was not required;

I further certify that I am not interested in the event of the action.

Witness my hand this 10 day of January

Certified Shorthand Reporter
for the State of California

DAVID J. STANOCH, ESQ.
D.STANOCH@KANNER-LAW.COM
January 10, 2023
RE: In Re: Valsartan, Losartan, Et Al v.
1/5/2023, Philip James Russ (#5648472)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-ny@veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al v.
Philip James Russ (#5648472)

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Philip James Russ Date

In Re: Valsartan, Losartan, Et Al v.
Philip James Russ (#5648472)

ACKNOWLEDGEMENT OF DEPONENT

I, Philip James Russ, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____

Philip James Russ Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____ DAY OF _____, 20___.

_____

NOTARY PUBLIC

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f

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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